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ABSTRACT

Hearings before the House Subcommittee on Health and the Environment on biomedical research and research training authorities that expire on September 30, 1978 are presented. H.R. 10908 is a bill to amend the Public Health Service Act to revise and extend the programs of assistance for libraries of medicine and the programs of the National Heart, Lung, and Blood Institute and the National Cancer Institute, and to revise and extend the program for national research service awards, and for other purposes. H.R. 10062 is a bill to amend Title V of the Public Health Service Act to provide for cancer research awards. H.R. 10190 is a bill to amend Title IV of the Public Health Service Act to provide for an expanded research program for the prevention of environmental and occupational cancer, and for other purposes. The full texts of the bills and statements of numerous spokesmen are presented. (SW)

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BIOMEDICAL RESEARCH AND RESEARCH TRAINING AMENDMENTS OF 1978

HEARINGS

BEFORE THE

SUBCOMMITTEE ON
HEALTH AND THE ENVIRONMENT

OF THE

COMMITTEE ON
INTERSTATE AND FOREIGN COMMERCE
HOUSE OF REPRESENTATIVES

NINETY-FIFTH CONGRESS

SECOND SESSION

ON

H.R. 10908

A BILL TO AMEND THE PUBLIC HEALTH SERVICE ACT TO REVISE AND EXTEND THE PROGRAMS OF ASSISTANCE FOR LIBRARIES OF MEDICINE AND THE PROGRAMS OF THE NATIONAL HEART, LUNG, AND BLOOD INSTITUTE AND THE NATIONAL CANCER INSTITUTE, TO REVISE AND EXTEND THE PROGRAM FOR NATIONAL RESEARCH SERVICE AWARDS, AND FOR OTHER PURPOSES

AND

H.R. 10062

A BILL TO AMEND TITLE V OF THE PUBLIC HEALTH SERVICE ACT TO PROVIDE FOR CANCER RESEARCH AWARDS

AND

H.R. 10190

A BILL TO AMEND TITLE IV OF THE PUBLIC HEALTH SERVICE ACT TO PROVIDE FOR AN EXPANDED RESEARCH PROGRAM FOR THE PREVENTION OF ENVIRONMENTAL AND OCCUPATIONAL CANCER, AND FOR OTHER PURPOSES

MARCH 1, 2, and 3, 1978

Serial No. 95-109

Printed for the use of the
Committee on Interstate and Foreign Commerce

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BIOMEDICAL RESEARCH AND RESEARCH TRAINING AMENDMENTS OF 1978

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MARCH 1, 2, and 3, 1978

Serial No. 95–109

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American College of Cardiology, Leonard S. Dreifus, M.C., F.A.C.C., president-elect.
American Federation for Clinical Research. (*See* Association of American Medical Colleges.)
American Federation of Labor and Congress of International Organizations:
  Clayman, Jacob, president, secretary-treasurer.
  Samuels, Sheldon, director, health safety and environment.
American Heart Association, W. Gerald Austen, M.D., president.
American Library Association, John A. Timour, on behalf of.
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American Nurses' Association, Constance Holleran, deputy executive director, government relations.
American Psychological Association, James S. Jackson, Ph. D., on behalf of. (*See* Association for the Advancement of Psychology.)
American Society for Hematology, William S. Beck, M.D., chairman, public information committee.

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- Association of American Medical Colleges:
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- Environmental Defense Fund, Joseph H. Highland, Ph. D., Chairman, Toxic Chemicals Program.
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- Memorial Sloan-Kettering Cancer Center, Lewis Thomas, president.
- New York and New Jersey Regional Medical Library, Alfred N. Brandon, director.
- Worcester Foundation for Experimental Biology, Mahlon Hoagland, M.D., president and scientific director.

BIOMEDICAL RESEARCH AND RESEARCH TRAINING AMENDMENTS OF 1978

WEDNESDAY, MARCH 1, 1978

House of Representatives,
Subcommittee on Health and the Environment,
Committee on Interstate and Foreign Commerce,
Washington, D.C.

The subcommittee met pursuant to notice, at 10:30 a.m. in room 2322, Rayburn Building, Hon. Paul G. Rogers, chairman, presiding.

Mr. Rogers. The subcommittee will come to order, please.

This morning the subcommittee will review the legislation to revise and extend the programs of assistance for libraries of medicine, the programs of the National Heart, Lung, and Blood Institute, the National Cancer Institute, and the research training program for the National Research Service Awards.

This morning is the first of a series of 3 days of hearings on H.R. 10908, H.R. 10190, and all similar bills to revise and extend these biomedical research and research training authorities which expire on September 30, 1978.

We have recently introduced this legislation. For instance, the biomedical research and research training amendments of 1978 propose a revision and 3-year extension of all the expiring biomedical research and research training authorities. H.R. 10190, the Cancer Prevention Act of 1978, introduced by Mr. Maguire, proposes a revision and extension of the authorities for the activities of the National Cancer Institute.

I would ask unanimous consent that the text of these bills, H.R. 10908, H.R. 10062 and H.R. 10190, be placed in the record at this point, and without objection it is so ordered.

[Testimony resumes on p. 25.]

[Text of H.R. 10908, H.R. 10062, and H.R. 10190 follows:]

95th CONGRESS
2d Session

H. R. 10908

IN THE HOUSE OF REPRESENTATIVES

February 9, 1978

Mr. Rogers introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

---

A BILL

To amend the Public Health Service Act to revise and extend the programs of assistance for libraries of medicine and the programs of the National Heart, Lung, and Blood Institute and the National Cancer Institute, to revise and extend the program for National Research Service Awards, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Section 1. (a) This Act may be cited as the "Biomedical Research and Research Training Amendments of 1978".

(b) Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Public Health Service Act.

TITLE I—LIBRARIES OF MEDICINE

Sec. 101. Section 390 (c) is amended by striking out "and" after "1976," and by inserting before the period the following: ", $15,000,000 for the fiscal year ending September 30, 1979, $16,000,000 for the fiscal year ending September 30, 1980, and $17,000,000 for the fiscal year ending September 30, 1981".

Sec. 102. Section 383 is amended (1) by striking out "by the President, by and with the advice and consent of the Senate" in the first sentence of subsection (a) and inserting in lieu thereof "by the Secretary", and (2) by striking out "by the President" in the first sentence of subsection (c) and inserting in lieu thereof "by the Secretary".

TITLE II—PROGRAMS OF THE NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Sec. 201. (a) Section 414 (b) is amended by striking out "and" after "1977," and by inserting before the period ", $40,000,000 for the fiscal year ending September 30, 1979, $45,000,000 for the fiscal year ending September 30, 1980, and $50,000,000 for the fiscal year ending September 30, 1981".

(b) Section 419B is amended by striking out "and" after "1977," and by inserting before the period the following: ", $460,000,000 for the fiscal year ending September 30, 1979, $505,000,000 for the fiscal year ending September 30, 1980, and $550,000,000 for the fiscal year ending September 30, 1981".

SEC. 202. (a) Section 413 (b) (2) is amended by striking out "submit to the President for transmittal to the Congress a report" and inserting in lieu thereof "submit a report to the Secretary, for simultaneous transmittal by the Secretary, not later than November 30 of each year, to the President and to the Congress,".

(b) Section 418 (b) (2) is amended by inserting "by the Secretary" after "transmittal".

SEC. 203. (a) Section 412 (5) is amended by striking out "make available" and inserting in lieu thereof "make available on a timely basis".

(b) Section 413 (d) is amended (1) by striking out "to provide" in the first sentence and inserting in lieu thereof "to provide on a timely basis", and (2) by striking out "diet" in the second sentence and inserting in ileu thereof "diet and nutrition, environmental pollutants".

SEC. 204. Section 415 (a) (2) is amended by adding after subparagraph (D) the following:

"(E) Programs of continuing education for health professions and allied health professions personnel in the diagnosis, prevention, and treatment of such diseases and information programs for the public respecting the prevention and early diagnosis and treatment of such diseases.".

TITLE III—PROGRAMS OF THE NATIONAL CANCER INSTITUTE

SEC. 301. (a) Section 409(b) is amended by striking out "and" after "1977," and by inserting before the period the following: ", $86,000,000 for the fiscal year ending September 30, 1979, $88,000,000 for the fiscal year ending September 30, 1980, and $90,000,000 for the fiscal year ending September 30, 1981".

(b) Section 410C is amended by striking out "and" after "1977;" and by inserting before the period the following: ", $924,000,000 for the fiscal year ending September 30, 1979; $927,000,000 for the fiscal year ending September 30, 1980; and $930,000,000 for the fiscal year ending September 30, 1981".

SEC. 302. Section 471 is amended to read as follows:

"APPOINTMENT OF THE DIRECTOR OF THE NATIONAL INSTITUTES OF HEALTH

"SEC. 471. The Director of the National Institutes of Health shall be appointed by the President by and with the advice and consent of the Senate.".

SEC. 303. (a) (1) Subsection (a) (2) of section 410B (a) (2) is amended by striking out "President" in subsections (a) (2), (b) (1), (b) (4), and (c) and inserting in lieu thereof "Secretary".

(2) (A) Subsection (a) of such section is amended by striking out "twenty-three" and inserting in lieu thereof "twenty-nine".

(B) Subsection (a) (1) of such section is amended by inserting after "Veterans' Administration" the following: ", the Director of the National Institute for Occuptional Safety and Health, the Director of the National Institute of Environmental Health Sciences, the Secretary of Labor, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Chairman of the Consumer Product Safety Commission".

(3) The second sentence of subsection (a) of such section is amended by striking out "and not more" and inserting in lieu thereof ", not more" and by inserting before the period ", and not less than three of the appointed members shall be individuals knowledgeable in environmental carcinogenesis (including carcinogenesis involving occupational and dietary factors)".

(4) Subsection (g) of such section is amended by striking out "a report to the President for transmittal to the Congress not later than January 31 of each year on the progress" and inserting in lieu thereof "a report to the Secretary, for simultaneous transmittal by the Secretary, not later than

November 30 of each year, to the President and to the Congress, on the progress during the preceding fiscal year".

(b) The amendments made by subsection (a) of this section respecting the manner of appointing members of the National Cancer Advisory Board and the composition of such Board shall apply with respect to appointments made to the Board after the date of the enactment of this Act, and the Secretary of Health, Education, and Welfare shall make appointments to such Board after such date in a manner which will bring about, at the earliest feasible time, the composition prescribed by such amendments.

SEC. 304. Section 410A (b) is amended (1) by striking out "end of each calendar year" and inserting in lieu thereof "end of each fiscal year", (2) by striking out "submit to the President for transmittal to the Congress" and inserting in lieu thereof "submit to the Secretary, for simultaneous transmittal by the Secretary, not later than November 30 of each year, to the President and to the Congress,", and (3) by striking out "the preceding calendar year" and inserting in lieu thereof "the preceding fiscal year".

SEC. 305. Subsections (a) and (b) of section 408 are each amended by striking out "clinical research, training, and demonstration of advanced diagnostic and treatment methods relating to cancer" and inserting in lieu thereof "clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods for cancer".

SEC. 306. Paragraph (7) of section 407 (b) is amended to read as follows:

"(7) Support appropriate programs of education (including continuing education) and training in fundamental sciences and clinical disciplines for investigators, physicians, and allied health professions personnel for participation in clinical programs relating to cancer, including the use of training stipends, fellowships, and career awards.".

TITLE IV—NATIONAL RESEARCH SERVICE AWARDS

SEC. 401. Subsection (d) of section 472 is amended by striking out "and" after "1977," and by inserting before the period at the end of the first sentence the following: ", $220,000,000 for the fiscal year ending September 30, 1979, $240,000,000 for the fiscal year ending September 30, 1980, and $260,000,000 for the fiscal year ending September 30, 1981".

SEC. 402. Subsection (a) (3) of such section is amended by striking out "as determined under section 473" and inserting in lieu thereof "as determined by the Secretary after review of the most recent results of the study prescribed by section 473 (a)".

SEC. 403. Paragraph (4) of subsection (b) of such section is amended to read as follows:

"(4) The period of any National Research Service Award made to any individual under subsection (a) may not exceed—

"(A) five years in the aggregate for predoctoral training, and

"(B) three years in the aggregate for postdoctoral training,

unless the Secretary for good cause shown waives the application of such limit to such individual.".

SEC. 404. The first sentence of subsection (b) (5) of such section is amended by inserting after "dependency allowances" the following: ", adjusted periodically to reflect increases in the cost of living".

SEC. 405. (a) (1) Subsection (c) (2) (B) of such section is amended by striking out "twenty months" and inserting in lieu thereof "twelve months".

(2) Subsection (c) (4) (A) of such section is amended by striking out "$A=\phi\left(\frac{t-1/2s}{t}\right)$" and inserting in lieu thereof "$A=\phi\left(\frac{t-s}{t}\right)$".

(b) The amendments made by subsection (a) shall apply only with respect to National Research Service Awards made under section 472 of the Public Health Service Act after the date of the enactment of this Act.

SEC. 406. Subsection (d) of such section is amended (1) by striking out "25 per centum" in the second sentence and inserting in lieu thereof "15 per centum", and (2) by inserting before the period "and not less than 50 per centum shall be made available for grants under subsection (a) (1) (B) for National Research Service Awards".

SEC. 407. Section 473 (c) is amended by striking out "not later than September 30 of each year" and inserting in lieu thereof "at least once every three years".

TITLE V—MISCELLANEOUS

SEC. 501. Section 301 is amended by adding after and below paragraph (h) the following:

"The Secretary may make available to indivduals and entities, for biomedical and behavioral research, substances, and living organisms if he determines that the substances or organisms to be made available are not otherwise available in sufficient quantity for such research or that by promoting uniformity in the substances and organisms used in such research there will be significant improvement in the results from it. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.".

SEC. 502. Section 439 (g) is amended by striking out the last sentence.

SEC. 503. Title IV is amended by inserting after section 476 the following new section:

"EXPERTS AND CONSULTANTS

"SEC. 477. The Director of the National Institutes of Health may obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the number of days or the period of service) the services of experts and consultants for the National Institutes of Health and for each of the research institutes (other than the National Cancer Institute and the National Heart, Lung, and Blood Institute). The number of experts and consultants which may be obtained under this section in any fiscal year may not exceed 2.5 per centum of the number of permanent employees employed in the preceding fiscal year in the National Institutes of Health and each of the research institutes (other than the National Cancer Institute and the National Heart, Lung, and Blood Institute).".

95TH CONGRESS
1ST SESSION

H. R. 10062

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 4, 1977

Mr. STAGGERS introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

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A BILL

To amend title V of the Public Health Service Act to provide for cancer research awards.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That title V of the Public Health Service Act is amended by adding at the end the following new section:

"CANCER RESEARCH AWARDS

"SEC. 514. (a) (1) The President is authorized to make an annual award to be known as the "President's National Cancer Research Award" to any individual who has conducted, during the calendar year preceding the year in which any such award is made, the project or projects making the most meaningful contribution in the United States to the prevention and treatment of cancer. Each recipient of such award shall receive an appropriate citation and a prize of $50,000, except that if more than one individual receives such award in any year, such sum shall be divided equally among all such recipients.

"(2) The President is further authorized to make an annual award to be known as the "President's State Cancer Research Award" to at least one individual residing in each State who has conducted, during the calendar year preceding the year in which any such award is made, a project making a meaningful contribution to the prevention and treatment of cancer. Each recipient of such award shall receive an appropriate citation and a prize of $5,000, except that if in any State more than one individual receives such award in any year, such sum shall be divided equally among all such recipients in such State.

"(3) The awards described in this subsection shall be made on the basis of recommendations submitted to the President by the National Cancer Advisory Board (hereinafter in this section referred to as the "Board") pursuant to subsection (b) (2) of this section.

"(b) (1) Each year the Director of the National Cancer Institute (hereinafter in this section referred to as the "Director") shall review, to the maximum extent practicable, the cancer research projects being conducted in the United States in order to determine whether any such project should be referred to the Board for consideration under paragraph (2) of this section. Not later than of each year, the Director shall refer to the Board any project which, in the opinion of the Director, deserves special consideration because of its significant contribution to the prevention and treatment of cancer. In making any such referral, the Director shall designate the individual or individuals responsible for conducting such project, and the Director shall provide the Board with a statement of reasons for such referral and such other appropriate supporting materials as the Board may request.

"(2) Each year the Board shall evaluate the projects referred to the Board by the Director pursuant to paragraph (1) of this subsection in order to determine which individuals, if any, should be recommended by the Board to the President for consideration for the awards described in subsection (a) of this section. The Board shall recommend to the President before October 1 of each year those individuals whom the Board has determined should receive such consideration and shall specify which award is appropriate for any individual so recommended. The Board shall include with its recommendations a statement of reasons for each recommendation and such other appropriate supporting materials as the President may request.

"(c) For purposes of this section—

"(1) the term 'State' means any of the several States and the District of Columbia; and

"(2) the term 'United States', when used in a geographical sense, includes the United States and any place subject to its jurisdiction.".

SEC. 2. Section 2 (f) of the Public Health Service Act is amended by inserting "514 (c) (1)," after "361 (d),".

95th CONGRESS
1st Session

H. R. 10190

IN THE HOUSE OF REPRESENTATIVES

December 1, 1977

Mr. Maguire introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

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A BILL

To amend title IV of the Public Health Service Act to provide for an expanded research program for the prevention of environmental and occupational cancer, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Cancer Prevention Act of 1978".

Sec. 2. Part A of title IV of the Public Health Service Act is amended—

(1) by striking out section 404 and by redesignating sections 405 through 409 as sections 404 through 408, respectively;

(2) in section 403 (c) by striking out "section 404" and inserting in lieu thereof "section 410B (d)";

(3) in section 406 (b) (4) (as so redesignated) by inserting "(A)" after "(4)" and by inserting before the period the following: "; and (B) conduct a study and submit a report to the Congress, not later than one year after the effective date of this subparagraph, of issues concerning and recommendations relating to the feasibility of establishing an integrated national data base or registry which would (i) assist Federal, State, and other appropriate agencies in locating persons exposed to carcinogens and referring such persons to appropriate health agencies, and (ii) facilitate studies of the effects of suspected carcinogenic substances on human beings";

(4) in section 406 (b) (1) (as so redesignated) by inserting "(A)" after "(1)" and by inserting before the period the following: "; and (B) implement an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens, which program shall include as appropriate animal and human epidemiological studies of chemical and physical substances";

(5) in section 407 (a) (as so redesignated) by amending the first sentence to read as follows: "The

Director of the National Cancer Institute may provide for the establishment of new centers for research, training, and demonstration of advanced methods relating to the prevention, diagnosis, and treatment of cancer.";

(6) in section 407 (b) (as so redesignated) by—

(A) striking out "clinical research, training, and demonstration of advanced diagnostic methods relating to cancer" and inserting in lieu thereof "research, training, and demonstration of advanced methods relating to the prevention, diagnosis, and treatment of cancer";

(B) striking out "section 405" and inserting in lieu thereof "section 404";

(C) striking out "and" before "(4)"; and

(D) inserting ", and (5) research into the identification and prevention of occupational and environmental cancer" after "(4) demonstration purposes";

(7) in section 407 (as so redesignated) by inserting ", including cancer caused by occupational or environmental exposure to carcinogens" after "cancer" wherever it appears;

(8) by amending section 408 (a) (as so redesignated) to read as follows:

"CANCER CONTROL PROGRAMS

"SEC. 408. (a) The Director of the National Cancer Institute, in cooperation with industry, labor, State, and Federal departments and agencies and other health agencies, shall establish programs in diagnosis, prevention, and treatment of cancer, including programs to identify and screen populations having a high risk for developing cancer because of occupational or environmental exposure to known or suspected carcinogens.";

(9) by adding after section 408 (as so redesignated) the following new section:

"COORDINATION WITH OTHER AGENCIES

"SEC. 409. (a) The Director of the National Cancer Institute, upon request of the head of any other appropriate entity of the executive or legislative branch of the Government of the United States, shall enter into a contract under subsection (c) of this section with the head of such entity to provide such entity with assistance in evaluating the carcinogenicity and mutagenicity of chemical and physical substances. In carrying out his duties under this section, the Director shall upon request assist the Administrator of the Environmental Protection Agency in evaluating and monitoring the testing conducted by nongovernmental laboratories under section 4 of the Toxic Substances Control Act by (1) studying the scientific quality of such testing, (2) reviewing the data and conclusions derived from such testing, (3) reporting the results of such studies and reviews to the Administrator, and (4) making such recommendations to the Administrator respecting such testing as the Director deems advisable.

"(b) The Director of the National Cancer Institute shall publish an annual report which contains—

"(1) a list of all known or suspected carcinogens to which a significant number of persons residing in the United States are exposed;

"(2) information concerning the nature of such exposure and the estimated number of persons exposed to such carcinogens; and

"(3) an evaluation of the efficacy of the existing regulatory controls designed to reduce or eliminate exposure to carcinogens, and recommendations respecting ways in which such controls could be improved.

"(c) If any entity requests assistance under subsection (a) of this section, the Director of the National Cancer Institute shall enter into a contract with the head of such entity for full reimbursement for the costs of providing such assistance.";

(10) in section 410(a)(8) by inserting ", and between the National Cancer Institute and any other appropriate entity of the executive or legislative branch

of the Government of the United States" before the semicolon;

(11) by amending section 410B (a) (1) to read as follows:

"(1) The Secretary, the Director of the National Institutes of Health, the Director of the National Institute for Occupational Safety and Health, the Director of the National Institute of Environmental Health Sciences, and the Chairman of the Council of Environmental Quality shall be ex officio members of the Board.";

(12) in section 410B (a) by striking out paragraph (2) and all that follows such paragraph and inserting in lieu thereof the following:

"(2) Twelve scientists or physicians, appointed by the Secretary from persons who are among the leading scientific or medical authorities outstanding in the study, diagnosis, or treatment of cancer or in fields related thereto.

"(3) Six appointed by the Secretary from the general public.

Of the members appointed under paragraphs (2) and (3) of this subsection, at least six members shall be appointed from among persons who are among the leading authorities with regard to cancer caused by occupational or environmental exposure to carcinogens. Any member appointed under paragraph (2) or (3) of this subsection shall be especially qualified to appraise the programs of the National Cancer Institute because of such member's training, experience, and background.";

(13) in section 410B(b)(1) by striking out "President" and inserting in lieu thereof "Secretary";

(14) in section 410B(c) by striking out "President" and inserting in lieu thereof "Secretary";

(15) in section 410B(d) by striking out the period and inserting in lieu thereof the following:

"and as appropriate make recommendations to the Secretary with respect to carrying out the provisions of this part. In carrying out its duties under this section, the Board shall—

"(1) review any intramural research project or program conducted by the National Cancer Institute and report to the Director of such Institute the results of any such reveiw;

"(2) review applications from any university, hospital, laboratory, or other institution whether public or private, or from individuals, for grants-in-aid for research projects relating to cancer, and certify to the Director its approval of grants-in-aid for projects which show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis or treatment of cancer, including occupational and environmental cancer; and

"(3) recommend to the Secretary for acceptance conditional gifts pursuant to section 501 of this Act.";

(16) in section 410C by striking out "section 409" and inserting in lieu thereof "section 408"; and

(17) in section 471 by striking out "section 407 (b) (9)" and inserting in lieu thereof "section 406 (b) (9)".

SEC. 3. (a) Except as otherwise provided in this section, the amendments made by section 2 of this Act shall take effect on the date of the enactment of this Act.

(b) (1) The amendments made by paragraph (12) of section 2 of this Act respecting the method of appointing members to the National Cancer Advisory Board and the composition of the Board shall apply with respect to the appointments made to the Board after the date of the enactment of this Act, and the Secretary shall make appointments to the Board after such date in a manner which will bring about, at the earliest feasible time, the Board composition prescribed by the amendment.

(2) The amendment made by paragraph (15) of section 2 of this Act respecting the designation of a Chairman by the Secretary shall take effect on the date of the termination of the term of the person who is serving as Chairman on the date of the enactment of this Act.

Mr. ROGERS. Today, the committee will first hear from witnesses representing the administration on the biomedical research and training programs of the National Institutes of Health and the behavioral research training program at the Alcohol, Drug Abuse, and Mental Health Administration, and on pending legislation to revise and extend these program authorities.

Later today the subcommittee will hear testimony from three distinguished panels of individuals and organizations. Do you have any remarks you might want to make, Mr. Maguire?

Mr. MAGUIRE. No, Mr. Chairman.

Mr. ROGERS. We are very pleased to have with us this morning representing the administration Dr. Donald S. Fredrickson, who is the Director of the National Institutes of Health, accompanied by David F. Kefauver, Acting Deputy Administrator, Alcohol, Drug Abuse, and Mental Health Administration; and Dr. Martin Cummings, Director of the National Library of Medicine; Dr. Robert I. Levy, who is Director of the Heart, Lung, and Blood Institute; and Dr. Arthur P. Upton, who is Director of the National Cancer Institute.

We welcome each of you to the committee, and your statements will be made a part of the record, without objection, and you may proceed.

STATEMENT OF DONALD S. FREDRICKSON, M.D., DIRECTOR, NATIONAL INSTITUTES OF HEALTH, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ACCOMPANIED BY MARTIN M. CUMMINGS, M.D., DIRECTOR, NATIONAL LIBRARY OF MEDICINE; ROBERT I. LEVY, M.D., DIRECTOR, HEART, LUNG, AND BLOOD INSTITUTE; ARTHUR P. UPTON, M.D., DIRECTOR, NATIONAL CANCER INSTITUTE; AND DAVID F. KEFAUVER, ACTING DEPUTY ADMINISTRATOR, ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION, PUBLIC HEALTH SERVICE

Dr. FREDRICKSON. Thank you, Mr. Chairman, Mr. Maguire.

It is a pleasure to be here today to discuss the legislative proposals which you have just summarized. The hearing, I think, comes at a particularly stimulating and challenging time for these research agencies which we represent, because the authorities to be extended account for more than one-half of NIH's program in budgetary terms at the present time.

There is a great need to understand what the research agencies are about, what we are doing, how we interact, and what are the legitimate expectations for our performance in the future. Certainly, opportunities for increasing the science base, which is our primary concern, have never been greater, and they also need to be coupled with the needs for special knowledge required of agencies who must be responsible for regulation, prevention, and health care, and financing all missions of the Department, and important problems for the country which are putting unprecedented demands upon us and those other agencies.

Certainly, before this committee I need not debate the importance of health research with regard to problems of health, nor will I even attempt to answer the question of how much research we ought to do, except to offer the opinion that I think we ought to do as much as the Nation can afford. Rather, I would like to mention briefly to the committee some of our recent efforts to improve our ability to describe the way in which the resources for health research are laid out across the country, particularly with relation to NIH [see p. 28].

We know we are in a time when basic science has gained a new emphasis by the administration, by Members of Congress, and by the community itself. One of the problems we have long faced and have attempted to do something different about this year is a definition of "basic" and "applied." It is very subjective, and no two people can agree.

This year we have been exploring a new approach to reclassifying our activities at NIH, one that I think takes into account the natural flow of activities across this huge terrain, which is the biomedical research continuum. We have started from one side of the mountains and rarefied atmosphere and the higher plateaus in the search for new knowledge which is often relatively undifferentiated becoming synthesized gradually, and which then falls into a plane of application which is certainly the direction and aim of all research, and finally, that boundary along the seashore where new ideas, new inventions emerging from research must embark upon their use in the population to benefit man. These several areas we have broken down into four major categories, the first being the search or efforts to increase the science base, the plane of applications, activities we call transfer, representing control and demonstration activities, and finally of training.

This is not a perfect categorization, but it has helped us, I think, this year, get a better grip on the deployment of resources for NIH as a whole and for each of the several institutes and divisions that make up its hegemony over this area of knowledge development.

I think that this will be a very useful base for sharpening the conceptual approach to how resources should be allocated, and very importantly, toward reaffirming the dual purposes of these research agencies to both discover knowledge and move it toward useful application.

I think if I might turn very briefly, Mr. Chairman, to the specific issues raised by the expiring authorities and proposed amendments, and not go into any detail about them, or to comment on each of the proposed amendments. H.R. 10908 would extend for 3 years the appropriations authorities for the National Cancer program, the National Heart, Lung, and Blood program, the Medical Library Assistance Act, and the National Research Service Awards.

We are pleased to see that the bill provides for a 3-year extension of these programs. For 1979, the administration favors authorization levels consistent with the President's budget as follows: for the NCI research and control programs, a total of $858.4 million; for the Heart, Lung, and Blood Institute research programs and its program for prevention, education, and control, a total of $432 million; for Medical Library Assistance, some $7.987 million; and for National Research Service Awards, the sum of $169.717 million.

The administration proposes authorizations of "such sums as may be necessary" for these programs in 1980 and 1981.

Mr. ROGERS. May I interrupt there to say it would be helpful if you could furnish adjusted figures as the committee will probably put in specific figures?

Dr. FREDRICKSON. We will provide them for the record and will be pleased to do so.

[The information requested was not available to the subcommittee at the time of printing.]

Dr. FREDRICKSON. The two bills under discussion also include several amendments to the aforementioned authorities as well as proposals for other changes in the NIH statutes. Certain provisions of H.R. 10908 have our support, including the following: Section 102, which authorizes the Secretary to appoint members of the National Library of Medicine Board of Regents; section 404, authorizing cost of living increases for NRSA stipends; section 405, amending the NRSA payback provisions to provide that all recipients would serve 12 months for each 12 months of support, and would receive proportional credit for partial fulfillment of the payback requirement; section 501, authorizing the Secretary to make available substances and living organisms for research purposes; section 502, deleting the requirement that 20 percent of funds for multipurpose arthritis centers be used to support new centers each year; section 503, authorizing appoinntment of experts and consultants for NIH components other than NCI and NHLBI, those two institutes already having such authority, and there are a number of other provisions in H.R. 10908 and H.R. 10190 about which we have no strong feelings or only modest reservations, and these are discussed in my more lengthy statement for the record.

Finally, Mr. Chairman, we are proposing repeal of an obscure and outdated provision of the PHS Act, section 321(a), requiring the Surgeon General to furnish tobacco to patients in PHS facilities. This requirement, which is presently honored more in the breach than in the observance, seems clearly inappropriate in view of our present knowledge about the effects of smoking on human health, and in fact in light of the current blitzkrieg of the Department, it is almost embarrassing.

This concludes my statement, Mr. Chairman, and my colleagues and I will be very happy to try to answer any questions you or other committee members may have.

[Testimony resumes on p. 41.]

[Dr. Fredrickson's prepared statement follows:]

FOR RELEASE UPON DELIVERY ONLY

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

STATEMENT BY

DR. DONALD S. FREDRICKSON

DIRECTOR, NATIONAL INSTITUTES OF HEALTH

ON

BIOMEDICAL RESEARCH AUTHORIZATION EXTENSIONS

BEFORE

THE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

HOUSE OF REPRESENTATIVES

March 1, 1978

Mr. Chairman and Members of the Subcommittee:

It is a pleasure for me to be here today to discuss H.R. 10190, H.R. 10908, and the Administration's current legislative proposals for the NIH. These include proposals for renewal of certain NIH legislative authorities expiring this year; renewal of the research training authorities shared by NIH and the Alcohol, Drug Abuse, and Mental Health Administration; as well as additional issues raised in legislation introduced by Chairman Rogers and Representative Maguire.

Appearing with me are Mr. David Kefauver, Acting Deputy Administrator of ADAMHA; and from the NIH are Dr. Martin Cummings, Director of the National Library of Medicine; Dr. Robert Levy, Director of the National Heart, Lung, and Blood Institute; and Dr. Arthur Upton, Director of the National Cancer Institute.

Mr. Chairman, this hearing comes at a particularly stimulating and challenging time for NIH. The authorities to be extended account for more than half of NIH's programs in budgetary terms.

The need to understand what NIH is all about--what we are doing, with whom we interact, and what are legitimate expectations for our performance--is a pressing one. Opportunities for knowledge development from the research perspective--when coupled with knowledge development needs of agencies responsible for regulation, prevention, health care, and financing--are placing unprecedented pressure on research agencies.

I will not attempt to debate today the importance of new knowledge to solutions of problems related to health. Nor can I answer the question of how much research should be done, except to say "as much as the Nation can possibly afford." Rather, I would like to mention to the Committee some of our recent efforts to improve our ability to describe the way in which we distribute our resources at NIH.

We have recently been exploring a new approach to classifying NIH activities, based on the categories "Science Base," "Applications," "Technology Transfer," and "Training." These categories encompass somewhat more than attempts to describe the intrinsic nature of scientific inquiry--historically a problem due to the highly subjective nature of such terms as "basic" and "applied." They also take into account other factors such as program goals and mechanisms of support.

These categories appear to hold considerable promise from an analytical standpoint, though our efforts along these lines are still very preliminary. We believe that they will provide a useful framework for sharpening the conceptual basis on which resources are allocated at the agency level, for interrelating research with other health missions of the Department, and for highlighting budgetary and other program issues at points of interface among the health agencies.

Let me turn now to specific issues raised by the expiring authorities and proposed amendments.

NIH Expiring Authorities

The Department is proposing a three-year extension of the authorities for the National Cancer Program, the National Heart, Lung, and Blood Program, the Medical Library Assistance Act, and the National Research Service Awards authorities. We appreciate, Mr. Chairman, the inclusion of a three-year extension for these programs in your bill, H.R. 10908. Insofar as these programs, by their very nature and by virtue of statutory requirements, entail a considerable amount of advance planning, it is our view that a three-year extension of the appropriations authorizations is necessary in order to assure stability and continuity. A three-year extension of the appropriations authorizations will allow the time to conduct the in-depth reviews desired by many in the Congress—reviews that we agree would be useful.

National Cancer Program

The past two years have been exciting ones for the National Cancer Program. Building on earlier efforts, the National Cancer Institute (NCI) is reporting significant progress in certain areas and promising leads in others. For example, the encouraging results of new treatments for childhood cancer, hinted at in the last decade, are holding up. It is now apparent that childhood leukemia, along with Hodgkin's disease and other lymphomas and cancer of the bone and kidney, can be treated with a reasonable expectation of cure. This success has been translated into a declining cancer death rate for all age groups under the age of 35.

In the fields of cancer cause and prevention, the NCI has, during the past two years, expanded its efforts in screening substances that pervade our atmosphere for cancer-causing potential. In cooperation with other Federal and non-Federal agencies, NCI has devoted expertise and resources to the recently established Clearinghouse on Environmental Carcinogens. Functions of the Clearinghouse include selection of chemicals for long-term bioassay studies, the experimental design for those studies, and an assessment of the data resulting from the studies.

During the past two years, data have been released on bioassay tests of several chemical substances. These findings have been provided to the National Institute of Occupational Safety and Health (NIOSH), the Occupational Safety and Health Administration (OSHA), and the Food and Drug Administration (FDA), and other regulatory Federal agencies for action.

Numerous epidemiological studies are going on as the result of a massive NCI survey of mortality rates in each county in the contiguous United States. Another aid to cancer epidemiologists was the publication in 1976 of the Cancer Patient Survival Report No. 5, which deals with patient longevity from selected hospitals across the country. Surveys and publications, such as these, give clues to cancer researchers about geographic causes of cancer and the effects of newer cancer treatments.

Cancer prevention is one of the most important goals of the National Cancer Program. For example, a clinical trial will soon be undertaken to test the value of a chemical relative of Vitamin A that scientists believe may reverse the action of known cancer-causing substances in tests on laboratory animals. In addition, basic research in cancer biology continues to yield much potentially useful information. Cell surface antigens, for example, have been shown to prevent the growth of cancers in experimental animals.

To continue these strides, we are proposing authorization levels for fiscal year 1979 of $62,583,000 for control and demonstration programs of the NCI, and $795,809,000 for the remainder of the NCI research programs. Our proposed authorization for fiscal years 1980 and 1981 is for such sums as necessary. Mr. Chairman, these authorizations are consistent with the President's 1979 budget, and with the desire of both the Administration and the Congress to provide balanced growth for all NIH institutes.

In addition to the authorizations extensions, H.R. 10908 and H.R. 10190 would make several substantive amendments to the authorities of the NCI. I would like to comment briefly on some of the more significant of these amendments.

1. The National Cancer Advisory Board. Both bills would make some significant changes in the membership of the National Cancer Advisory Board. H.R. 10190 would add, as ex officio members, the Directors of the National Institute of Occupational Safety and Health, the National Institute of Environmental Health Sciences, and the Chairman of the Council on Environmental Quality. H.R. 10908 would add the Directors of NIOSH and NIEHS, the Secretary of Labor, the Commissioner of the FDA, the Administrator of the Environmental Protection Agency, and the Chairman of the Consumer Product Safety Commission. We agree that increased collaboration with regulatory agencies is desirable, and I have already mentioned some of our efforts in that direction. On the other hand, we are concerned that a greatly enlarged Board might prove unwieldy.

Similarly, with regard to appointed members of the Board, we agree with the intent of both bills to ensure adequate representation of experts in environmental and occupational carcinogenesis. In our view, the designation of three such members, as proposed in H.R. 10908, is more appropriate than the six specified by H.R. 10190.

Finally, Mr. Chairman, we have no objection to the provision in H.R. 10908 providing for Secretarial, rather than Presidential, appointment of Board members.

2. Emphasis on prevention. Both bills would amend the comprehensive centers authorities to specify "prevention" as a responsibility of cancer centers. As I have noted, we are placing increased emphasis on cancer prevention. Similarly, H.R. 10190 would highlight prevention as an objective of the National Cancer Program and as an element of NCI's control programs. While we have no objection to these provisions, we feel that our current programs are responsive to the intent of the legislation.

National Heart, Lung, and Blood Program

For more than 50 years, heart and blood vessel diseases have been the major cause of death in this country. In 1976 they accounted for over 50 percent of all deaths, nearly three times the death rate from cancer, the next highest cause. An estimated 30 million persons in the United States have diseases of the heart and blood vessels. The result of this high burden of acute and chronic illness and disability on the Nation's economy is staggering. According to recent data on this economic burden from the National Center for Health Statistics, diseases of the heart, circulatory, and respiratory systems rank first or second in seven of the eight indices measured. In the context of these sobering statistics, however, significant improvements are being observed. From 1970 to 1976, the deaths due to cardiovascular disease have declined by

14.6 percent -- more than twice the decline from non-cardiovascular disease. In 1975, the number of deaths from major cardiovascular disease dropped below one million for the first time since 1964, despite an increase in population and the growing proportion of senior citizens.

There is reason to believe that the National Heart, Lung, and Blood Institute's program strategy which spans the continuum of research activities from fundamental knowledge acquisition and clinical validation to education, demonstration, and control activities has contributed to this success in reducing mortality.

Fundamental knowledge is the prerequisite for the development of methods for the prevention and treatment of disease. Prostaglandins, a ubiquitous group of minute chemical compounds in the body, have recently been implicated in the cause of hypertension, the triggering of the atherosclerotic process, the management of congenital heart diseases, and the prevention of complications of asthma.

Clinical validation trials supported by NHLBI, such as the examination of the long-term benefits of coronary artery bypass surgery versus medical care, have the potential for enormous savings in health care costs; while others, like the trial to test the efficacy of prophylactic use of antiarrhythmic drugs to prevent fatal cardiac arrhythmia, have the potential to save thousands of lives.

The Institute's prevention, education, and control efforts have expanded from a primary concern with the efficient dissemination of information to an involvement in research on motivation, health behavior, and alternative educational strategies designed to influence health behavior. The success of a model program, the National High Blood Pressure Education Program, can be measured by a marked increase in the number of patient visits to physicians for hypertension detection. Simultaneously, there has been an enormous increase in patients now under effective blood pressure control and a precipitous decline in nationwide hypertension-related mortality statistics. Patient education can contribute greatly to the effective treatment of such conditions. H.R. 10908 would provide minor changes in NHLBI's authority in information dissemination. These changes would be consonant with the Institute's continuing objective of emphasizing timely dissemination relative to all risk factors for cardiovascular, lung, and blood diseases.

To fund these important activities of the National Heart, Lung, and Blood Institute, we propose appropriations authorizations as follows: for fiscal year 1979, $28.9 million for prevention, education, and control programs, and $403,284,000 for research programs; for fiscal years 1980 and 1981, we recommend such sums as are necessary.

National Library of Medicine

Also expiring this year are the provisions of the Medical Library Assistance Act, the authority for all extramural programs of the National Library of Medicine (NLM). Programs administered under this authority include grants for medical library resource improvements, research projects, training, research and demonstrations, special scientific projects, and publications, as well as contracts to regional medical libraries. Through these programs, the NLM plays a major role in disseminating biomedical information and strengthening the capabilities of medical libraries around the Nation.

The Library is expanding its extramural research program to investigate new applications of computer technology to health science information systems. In addition, the Library will continue expansion of the Regional Medical Library Network to reach community hospitals and other local health facilities, thereby providing information access for health professionals in remote or underserved areas.

For these programs, Mr. Chairman, we recommend an authorization level of $7,987,000 for FY 1979, and such sums as are necessary for FY's 1980 and 1981. In addition, we support the provision in H.R. 10908 authorizing the Secretary to appoint members of the NLM Board of Regents.

National Research Service Awards

Another expiring authority of major significance for the programs of NIH, the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), and the Health Resources Administration's (HRA) Division of Nursing is the National Research Service Award Program. Authorization for this program provides the only authority for research training for these Public Health Service components.

We are proposing a three-year extension of this authority at the following levels: $169,717,000 for FY 1979, and such sums as are necessary for FY's 1980 and 1981. Because of the lead time involved in developing research training programs and the need for potential trainees to have some assurance of continued support, it is imperative that this authority be extended for a reasonable period of time.

Several amendments proposed in H.R. 10908 have a great deal of merit. For example, we support the notion of allowing the Secretary to make periodic adjustments to NRSA stipends to reflect changes in the cost of living, at his discretion.

We also support your proposed amendments to the service payback requirement. As you know, the present formula provides that any recipient who fulfills part of the service requirement, but fails to satisfy it entirely, is penalized in that he or she is only given half credit for partial service. This arrangement is inherently inequitable and is serving to deter able people from entering into research training programs under NRSA auspices. We support H.R. 10908's amendment to the formula that would provide proportional credit for partial completion of the service payback. Secondly, the Act presently recognizes that positions in research or teaching may not be available for all NRSA recipients and provides several other options for completion of the service requirement. However, the present statute effectively discriminates against those who must choose certain options among those offered in that it imposes a requirement of 20 months for every 12 months of support in contrast with the requirement for teaching or research which amounts to 12 months for each 12 months of support. Again, we support a change to treat all recipients on an equal basis and require straight one-for-one payback regardless of the form of service.

A final concern about the research training program relates to the decline in applications for support of training in clinical research. Recent increases in salaries for interns and residents, coupled with the imposition of service payback requirements, appear to have diminished the attractiveness of research training programs for recent M.D. graduates. We do not know at this point if the problem is amenable to quick solutions through legislative or other means. The changes in the payback provisions, if enacted, may go a long way in that direction.

Additional Amendments and Proposals for New Authorities

I would like to comment briefly on certain other provisions of H.R. 10908, as well as an additional proposal we are submitting for your Committee's consideration:

1. Repeal of 20% arthritis center set-aside. We support H.R. 10908's amendment to the present provision in section 439(g) of the PHS Act, requiring that 20% of funds available for support of multi-purpose arthritis centers be made available each year for support of new centers. The effect of this requirement on the centers program is potentially very destructive. The effect of a cumulative 20% earmark for new centers will be to preclude adequate support of established centers, and we urge repeal of this provision.

2. Distribution of chemicals and animals. The NIH currently has limited authority to make available certain research materials to investigators requiring them. For example, NIH may provide biological materials such as vaccines and standard reference materials for research involving biological products. H.R. 10908 includes an amendment to section 301 of the PHS Act to permit the Secretary to make available substances and living organisms in instances where such materials are not commercially available or must be provided on a centralized, standardized basis. We support this authority, which would remove limitations that have proved troublesome for several NIH components, particularly the National Cancer Program.

3. Appointment of experts and consultants. Also included in H.R. 10908 is an amendment that would provide the Director of NIH with authority to appoint experts for extended periods--an authority presently available only to the Directors of NCI and NHLBI. The bill would fix the number of such experts and consultants at 2.5 percent of permanent NIH employees (excluding NCI and NHLBI). In our view, this authority would provide excellent opportunity to secure top-flight scientists/administrators to assist in developing new programs and to work on selected research projects requiring very specialized background. A recent survey showed that the Institutes could productively use many such experts, and the NIH developed a legislative proposal to authorize the Director to appoint up to 300 such consultants. We would prefer a fixed number as originally proposed.

4. Finally, Mr. Chairman, we are proposing repeal of an obscure and outdated provision of the PHS Act [Section 321(a)] requiring the Surgeon General to furnish tobacco to patients in PHS facilities. This requirement--which is honored more in the breach than in the observance--is clearly inappropriate in view of our present knowledge about the effects of smoking on human health.

This concludes my statement, Mr. Chairman. My colleagues and I would be happy to try to answer any questions you or other Committee members may have.

Mr. Rogers. Thank you very much for your statement, and for the indication of support for the legislation.

Mr. Maguire?

Mr. Maguire. Thank you, Mr. Chairman.

Dr. Fredrickson, on page 6, at the top, of your written statement, you refer to the two bills, indicating that you prefer the version which provides that three members should be experts in environmental, occupational carcinogenesis as opposed to six. I was just wondering why you felt that way.

Dr. Fredrickson. I think, Mr. Maguire, our preference there is related entirely to a matter of quantification. We felt it might be undesirable to expand the board to too large a size. Nevertheless, I think the suggestion for the addition of expertise that you propose is a very good one.

Mr. Maguire. In my bill, I do not expand the size of the board at all. I am simply suggesting that out of 23 members, I believe it is, is it not, that we have six who are experts in this field. Given we are now told by scientists that 60 to 90 percent of cancer is caused by exposures of one sort or another to environmental influences, perhaps it would not be an inordinate number to have approximately one-quarter of the members of the board experts in that particular area.

Dr. Fredrickson. Certainly, we think we ought to try to do that as much as possible, Mr. Maguire. It does make it perhaps difficult without expanding the board to retain the balance of other expertise or input that will cover the rest of the program, and that was our only concern. The suggested emphasis, I think, however, is an excellent one.

Mr. Maguire. So you are not going to make three versus six a sticking point?

Dr. Fredrickson. I think, Mr. Maguire, our preference there is

Mr. Maguire. Unless someone can describe pretty clearly to me what is going to be lost as a result of making this expansion, I am going to try to insist on that, and we will be prompted to some degree by the amount of resistance we encountered. I hope it won't be too much.

Dr. Fredrickson. I think it will be barely perceptible, Mr. Maguire.

Mr. Maguire. Excellent.

I am interested in the numbers you have given at the bottom of page 4 and the top of page 5, for what you describe as control and demonstration programs, some $62 million, and the remainder of the research program, $795 million. The dicussion of control and demonstration comes within the context, I assume, of the previous paragraph, where you are talking about prevention, and I just wondered whether in that context control and demonstration means prevention-oriented programs, or whether it does not. What does it mean, exactly?

Dr. Fredrickson. I will let Dr. Upton answer that, but I think, Mr. Maguire, one thing is certain. It is not intended to represent the only effort toward prevention or to circumscribe that effort by that subappropriation.

Dr. Upton?

Dr. Upton. Mr. Maguire, the budget figure given for control is the budget allocation which funds the Division of Cancer Control and Rehabilitation. The efforts there are aimed largely at technology transfer, not just in prevention but in treatment.

Mr. Maguire. So this really does not follow from the preceding paragraph at all?

Dr. Upton. It does not, no.

Mr. Maguire. Why don't you complete your explanation? That will be useful, and we can discuss it further.

Dr. Upton. Within the technology transfer area we are seeking to emphasize those activities which relate to preventive strategies—screening of populations at risk, worker education in relationship to occupational cancer risks, and so on. I the research area, we are likewise intensifying our efforts to identify environmentally causes of cancer and to develop means for intervening to remove them from the environment or to prevent their action.

Mr. Florio. Will the gentleman yield?

Dr. Upton. The carcinogenicity testing program is not funded out of the cancer control budget, but it is funded out of the research budget. That is an example of a testing effort aimed directly at prevention, which does not fall within the $63 million figure.

Mr. Florio. Will the gentlemen yield on that point?

Mr. Maguire. Certainly.

Mr. Florio. With regard to this whole question of interagency cooperation, EPA now is late in coming up with rules and regulations under the Toxic Substances Act regarding PCB's. Part of the rationale they provided about being late is that they have not the expertise. Hence, they have not been able to come up with the information they need to develop realistic regulations.

What, if anything, are you doing in dealing with some of these other agencies that maintain they haven't the scientific base they need, for example, be it EPA on PCB's, or be it OSHA with regard to its new initiative into occupational disease? Is there any interaction between yourself and some of the other agencies?

Dr. Fredrickson. I would speak in general, and allow Dr. Upton and others to comment further. There is a great deal of interaction. There are some 11 to 14 committees related to questions of the environment, providing interfaces between various components of the Department and regulators, and in which we play a certain role. We are members of the committee described under TSCA to help select those compounds that shall be among those tested. The Clearinghouse on Environmental Carcinogens contains representatives from all the regulatory agencies, and they play a very important part in helping to select and to keep them fully informed of the movements of compounds along the lines of that critical program for which NCI is primarily responsible.

Nevertheless, we are not content with the perfection of that interaction either. I think one of the major items under discussion in the Department, at NIH, and elsewhere today, and also with the regulated group, is, how can we better provide the information needed by those agencies? There are a number of philosophical questions involved. How does one maintain a science base? What kinds of research can best be done by regulatory agencies? Which kind cannot be done very well for a variety of reasons? If it can't be done by them, how does NIH or ADAMHA begin to provide an arrangement whereby they can purchase, if we may use that term, the information they need?

For example, today the regulator, FDA, has a question about saccharin, very close to this committee and other's interest. It has devised an interesting cross-agency agreement whereby it transfered some three-quarters of $1 million to the Cancer Institute to provide the kind of epidemiologic information that may help it resolve this important regulatory question.

There are a whole host of these, and we are very interested in seeing how within NIH we can arrange our environmental groups particularly and all of the groups that have reseearch that is of importance to the problems of regulators, to see how we can do that more effectively, get more out of the same animal, for example, in terms of toxicity questions.

At the same time, how can we arrange an even better "board of directors" of such activities that would include all the regulators who need that knowledge as well as the researchers whose expertise is needed to make that the best possible effort? We are aware of this question. We do not have perfect arrangements, but we have multiple ones which are working, I think, every day.

Mr. FLORIO. Thank you.

Mr. MAGUIRE. Thank you.

Dr. Fredrickson, on page 6 of your statement, halfway down, you nod graciously in the direction of my bill's highlighting of prevention as an objective, but go on in effect to say that you feel your current programs are responsive to that concern. Let me put the question another way.

Would you feel any discomfort if we were to make that concern more explicit in the basic act than it has been in the past?

Dr. FREDRICKSON. No; we would not, Mr. Maguire. I think that what our statements here refer to is our belief that we find this to be one of the reasonable responsibilities of cancer centers, that prevention must be a part of their efforts, even narrowly defined, and that we had under our current authorities sufficient expression of intent, but we would have no objection at all, as far as I am concerned, to a reemphasis on the part of the interest and intent of the committee in this regard.

Mr. MAGUIRE. I would like to ask you and perhaps Dr. Upton as well whether or not it is your intention to expand and intensify your activities with respect to preventive strategies beyond what they have been in the past. There has been a lot of criticism in the recent past on the point that out of some $800 million plus annual budgets, there has not been enough emphasis on screening of carcinogenic substances. There has not been enough emphasis on looking carefully at the populations that are at highest risk, and in general, given that cancer is difficult to deal with once people get it, and we now know that so much of it is the result of exposures of one sort or another, as I mentioned earlier, that we really need an expanded and intensified set of activities in respect to prevention.

Is it your contention today that everything is fine and you are doing just fine, and the intent of the legislation is clear, and that the current allocations in the field of prevention are adequate within the context of the total budget, or is it your intention to expand on the preventive side?

Dr. **Fredrickson.** If I might answer in general, I will then turn to Dr. Upton. I might say I think our current legislation specifies intent. At least we infer from that legislation the intent to move all we can toward prevention. I do not think that we should infer that we are doing fine. We are not. We would like to know a lot more about cancer and to do a lot more about it than we have been able to do.

I think that certainly this matter of distribution of resources, their allocation toward movements of prevention against other applications, chemotherapy, for example, or other purposes, as well as the question of the relative shift of support within the Cancer Institute towards basic science, which is an important theme of this year, is a matter of continuing discussion between Dr. Upton and myself and a matter of the highest interest, too, at NIH.

I think we have the legislative authority. I think we have difficult decisions to make, and I am particularly conscious of the question of whether or not the Cancer Institute's program for whole animal testing of carcinogenic capacity for chemicals is an adequate expression of both their own program and meets the needs of the country. As a matter of fact, Dr. Upton and I are both convinced that it is not, and we are now working closely with other parts of the Department, with the Secretary, to see if we can expand that capacity, and to share the responsibilities and opportunities for performance that we think are necessary, because it is a national resource.

I have noted in the review of the Cancer Institute this last year which I conducted, the Cancer Institute has more than $100 million in its budget of what we might call service programs, programs that may not move the cutting edge of new knowledge, but which have to be performed for the country. One of these is the testing program of $15 to $20 million. Another, for example, is a whole pharmaceutical program for developing chemotherapies that we cannot expect from industry.

So, I think this is a burden that NCI must bear. It is very appropriate for it to be related strongly to its programs, but I think we are conscious of this in attempting to shift to prevention as much as we can, but I would let Dr. Upton speak more specifically for himself in that regard.

Mr. **Maguire.** Dr. Upton?

Dr. **Upton.** Mr. Maguire, I would support wholeheartedly everything that Dr. Fredrickson has said. We have undertaken a series of reviews of our activities in the prevention area. We have held a a number of meetings involving several Nobel laureates and other scientists who are expert in the field. We have planned a series of conferences to examine opportunities and ways in which we may be more effective in this area.

I have asked our Clearinghouse to undertake a thoroughgoing review of the bioassay program—past, present, and future—for the purpose of determining what in its view needs to be done.

Mr. Maguire. My bill suggests some rather specific requirements and outcomes that go beyond what have previously been present in the basic legislation, and I just wondered if you would be sympathetic to some more explicit language.

For example, it seems clear to me that with the variety of agencies involved, and we could have clearinghouses from now until doomsday, that somebody has to have responsibility, and it seems to me that that somebody ought logically to be the National Cancer Institute. I am talking about responsibility for coordination and cooperation between themselves and other agencies, and specifically I would require that NCI conduct an evaluation of the carcinogenicity of any substance at the request of another agency, although the other agency would be asked to pay for that out of its budget, but where there is a question raised, a serious question about a substance, that someone finally be responsible for making sure that the the work is done. As you well know, we have had a situation in which we have had literally hundreds, if not thousands, of substances which are either known or suspected to be highly hazardous at large, and you have done 8 of them, and someone else has done 10, and we are talking about hundreds of thousands of substances. Why should we not in the law establish that the NCI is the final responsible body here with respect to coordination, making sure that we get the job done, and whenever anyone asks for it, making sure the work is in fact performed?

Why should we not have an annual report, a requirement that we have a report each and every year from NCI with respect to all known and suspected carcinogens, estimating the dangers and making some assessment of the exposures, and making an evaluation of the existing regulatory situation and recommendations?

Those are things I have specifically suggested in my bill, and I would like to have your reaction.

Dr. Fredrickson. Mr. Maguire, if I might react in the general sense, I think the problems you seek to solve must be solved. The question of disaggregation of all testing is a very serious problem. You cannot get it all together probably because it is too complicated, but we need to do as much as we can in that direction.

What I would hope is, however, that you not create some statutory requirement in your legislation that this necessarily be done in the National Cancer Institute, and I will tell you the reason for that.

Mr. Maguire. Is there a better place to do it?

Dr. Fredrickson. There may be. I think at the moment the Cancer Institute is doing a wonderful job, the best that they can, against the current arrangements.

Mr. Maguire. Clearly, you have already said, and I agree, that we are not doing what we ought to be doing. So, the questions is, how do we get there, and unless someone is responsible, I suggest and submit we will not get there.

Dr. Fredrickson. Let me further expand on what I mean. That is, the Cancer Institute is now testing for carcinogenicity of compounds, and yet we know that the toxicity of most compounds does not relate to oncology, but to other serious side effects. At the present time, we are not looking at more than one adverse side effect of exposure to any chemical. I think that is wrong and inefficient.

We ought to see if there is a way through some consortial arrangement that we can get together the examination of overall toxicity, or at least more global approach to the implication of certain compounds. It may be that we need some sort of consortial arrangement, whether it be within the NIH in its several institutes, or whether it should be in some other arrangement, a problem which we are actively exploring and seeking options to now.

I would simply hope that your legislation would in some way express that intent to get it together, to maximize, to increase the capacity for testing, but if you were to create a situation in which this would have to be carried out by the Cancer Institute, of course, the options we would have for making better arrangements in our view and, of course, defending or supporting them, would be narrowed considerably. That is all.

Mr. Maguire. The options might be narrowed, but you can choke to death on multiple options, and never establish any clear responsibility and accountability. I mean, do you have an alternative proposal? This has been discussed for months and months, years and years. Do you have an alternative proposal which you would like to set before the committee?

Dr. Fredrickson. Not at this time, Mr. Maguire.

Mr. Maguire. Dr. Upton, would you like to comment as Director of the NCI? Perhaps you would like to comment on your attitude, given that you had $800 plus million, which is more than anyone else has in this area, toward assuming some of these more specific responsibilities. Let us neutralize the question for the moment of whether or not we are dealing with a multiplicity of effects. That is a well taken point, one which I am concerned about as well. I am really addressing the question of whether or not it might not make sense to make an annual report, whether it might not make sense to have someone obliged to test a given substance when some agency determines that there is a probable hazard, and whether or not there ought not be someone who is in charge of coordination.

If everyone is in charge of coordination, we will never have any.

Dr. Upton. Mr. Maguire, I agree with what you have said. I think there is a national need for this. There is a need to unambiguously focus responsibility for it, and I submit to you that we have recognized the need and have entered into discussions aimed at the development of the best plan of action. Whether, as Dr. Fredrickson has indicated, the responsibility should be lodged in NCI or in some other agency—a regulatory agency or another research agency, the National Institute of Environmental Health Sciences, for example—remains to be determined, but I would agree that the thrust of your proposal makes eminent sense.

Mr. Maguire [presiding]. Mr. Florio, do you have any comments?

Mr. Florio. Yes. One of the things I am interested in, and I think you can perhaps understand the intensity of Mr. Maguire's and my concern about this particular subject, is as follows: Coming from New Jersey, my own district unfortunately has an extremely high rate of cancer incidence. One county in my area has the highest incidence of bladder cancer in the entire Nation, so we have a vested interest in seeing that everyone does what they have to do. For example, lets talk about the minicenters. My recollection is that New Jersey did apply for a grant to operate a minicenter within our State. Can you give me the status of that grant application?

Dr. UPTON. I am sorry, I cannot at the present time. I could submit it for the record.

[The following information was received for the record:]

Grant application Number 1-R18-CA-24248-01, submitted by Dr. Mark A. Quinones of the College of Medicine and Dentistry of New Jersey, currently is under review. It is anticipated that this application will be submitted to the National Cancer Advisory Board for their consideration in May 1978.

Mr. FLORIO. I would appreciate it. My recollection is that there was some planning money approved, but no great followup after the initial planning money. I am also interested in the specific point I raised before, if there is anyone here who can specifically tell me about the PCB problem. EPA, as of last October, was supposed to publish regulations on PCB's. They have said that they did not have the scientific data. If there is some way you might be able for the record to get to me what you have done and what you plan to do to assist them in coming forth with these regulations, I would appreciate that as well.

Dr. FREDRICKSON. We will supply that, Mr. Florio.

[The following information was received for the record:]

We have discussed this question with the Office of Toxic Substances of EPA. We are informed that they have the required health data in hand. Further, we are told that the delays in promulgating the regulations resulted from the need to develop a variety of information much of which was of a technical and engineering nature. Among the questions to be answered were: How is each type of PCB containing material to be disposed of? What are the various uses of PCBs? What is the economic impact of regulation of these compounds?

EPA has moved forward and published the first of the required regulations on March 17, 1978.

Mr. FLORIO. Shifting to a different topic, legislation has been enacted for the establishment of national alcoholic centers. These centers are going to bring together various disciplines for research into the problems of alcohol. Are you having any input into the establishment of these centers? If so, what do you see as the relationship between what the National Institutes of Health is doing in terms of alcohol research and what these centers are supposed to be doing?

Dr. FREDRICKSON. Mr. Kefauver is here from ADAMHA, where this activity is primarily lodged, as you know, Mr. Florio, that being the National Institution on Alcohol Abuse and Alcoholism of ADAMHA. We specifically are not at this time, as far as I know, acting in any active way with regard to the establishment of these particular centers.

Mr. KEFAUVER. These centers you have referred to are primarily or solely directed at research. They are research centers, with an interdisciplinary focus, to focus on the behavioral and biological aspects of alcoholism. They are not in that sense prevention or control programs.

Mr. FLORIO. My point is not about what you do in terms of research? Specifically, you are not into alcoholism control. You are into research and my point and my concern is that we not have duplication; and, rather than have some autonomous new system evolve that will be doing the same things you are doing, maybe that could be headed off by virtue of your becoming involved in the establishment and setting up of these centers to see that duplication is avoided.

Mr. **Kefauver.** The research collaboration between the National Institutes of Health and the National Institute of Alcohol and Alcohol Abuse is quite close in terms of collaborative research, in terms of the knowledge of what each institute is doing, but the effort to fund national alcohol research centers is an ADAMHA initiative.

Mr. **Florio.** It is?

Mr. **Kefauver.** Yes.

Mr. **Florio.** So I assume then that there is some ongoing relationship between the establishment of these centers and what is going to be done in them and what is being done in the alcohol abuse facility.

Mr. **Kefauver.** Yes. I am not certain—the alcohol abuse facilities you are talking about are treatment centers?

Mr. **Florio.** No, your National Alcohol and—I forget. You—indicating Dr. Fredrickson—made reference to it a few moments ago.

Dr. **Fredrickson.** NIAAA.

Mr. **Florio.** NIAAA. What I am suggesting is that the centers that are being established—for example, I understand Rutgers University will be accepted as a new center, and I applaud that, need to be closely coordinated with the activities and functions of both the NIH and the NIAAA.

Mr. **Kefauver.** There is close coordination between NIAAA and those centers.

Mr. **Florio.** What exactly is the relationship between the two?

Mr. **Kefauver.** The centers are funded by NIAAA. They are monitored by project officers, much more closely than is the usual grantee agency relationship, so that the planning that goes on in those centers, the conduct of the research fully involves the Institute, and it is on an annual evaluation schedule where the Institute and other outside organizations will be evaluating the activities of the centers.

Mr. **Florio.** Thank you. There is a question that Mr. Rogers would ask. How many medical and health sciences libraries are there in the United States? How many of these have received assistance under the Medical Library Assistance program?

Dr. **Fredrickson.** We will ask Dr. Cummings.

Dr. **Cummings.** There are approximately 4,000 medical libraries in the United States, and somewhat over 500 have now received assistance through the Medical Library Assistance Act.

Mr. **Florio.** How many hospitals are reached?

Dr. **Cummings.** The major number of libraries are in community hospitals. I would estimate that except for 120 health professional school libraries, nearly all of the others are in either large or small community hospitals.

Mr. **Florio.** This is another question Mr. Rogers would ask. Do we have a shortage of toxicologists and veterinary pathologists or other personnel involved in the testing of substances in our environment? If so, what is the extent of the shortage in each category?

Dr. FREDRICKSON. Mr. Florio, everyone seems to agree that there is a shortage. It is an anecdotally supported shortage. We do not have adequate figures for the number of people operating in that area or how many are even being trained by all the possible agencies. It is apparent, however, when one seeks to establish a research program requiring a veterinary pathologist, it is extremely hard, almost impossible to find one. The same is true for toxicologists, but we do not have adequate figures to indicate how severe that shortage is.

The NIH does have a WESTAT study looking at different kinds of professional competence now available. This includes epidemiologists and, I believe, toxicologists. I hope we can have this year some more useful information.

Mr. FLORIO. Thank you very much.

Mr. MAGUIRE. Dr. Carter?

Mr. CARTER. Thank you, Mr. Chairman.

According to your best research available, what is your present treatment of alcoholism?

Mr. KEFAUVER. I do not think that we could cite a particular treatment, Dr. Carter, but as you are probably aware, the treatment options are counseling, antabuse, and combinations of those approaches. Of course, the Alcoholics Anonymous approach is also widely used.

Mr. CARTER. That has been around for many years now, has it not?

Mr. KEFAUVER. Yes, sir.

Mr. CARTER. Yet we are still using it, and nothing further other than counseling and——

Mr. KEFAUVER. Psychotherapy.

Mr. CARTER. We have been doing that for many years.

Mr. KEFAUVER. That is right. There is at the present time no——

Mr. CARTER. What is the characteristic of a patient who is on antabuse and takes a drink of whiskey?

Mr. KEFAUVER. It is my understanding that such a patient becomes nauseated, ill.

Mr. CARTER. They become red in the face, and their pulse increases. The rate increases and it scares the heck out of them. That is what happens. Did you ever see one?

Mr. KEFAUVER. No sir, I have not.

Mr. CARTER. Doctor, I think you ought to see some of those. After all, you are the director of this program.

Dr. FREDRICKSON. Dr. Carter, Mr. Kefauver is doing magnificently actually, in light of the fact that he is a deputy administrator without a medical degree.

Mr. Carter. You know, I think he ought to know something about antabuse. Have you ever seen a patient who has reacted to antabuse?

Dr. FREDRICKSON. Yes, I remember when we were interns that we had such patients.

Mr. CARTER. How did a typical patient react?

Dr. **Fredrickson.** He did very poorly, but whether it actually worked——

Mr. **Carter.** Describe his condition.

Dr. **Fredrickson.** A drop in blood pressure. He became lightheaded, nauseated, did indeed, as you say, develop, along with that redness of the face, an increase in pulse, and the was extremely anxious.

Mr. **Carter.** Yes, sir, that is one of the characteristics. Really, if you keep them on that quite a while, you usually can save them, can rescue them from their habit. There is another little saying that I have observed to be true quite often, that you have to let them hit the bottom before they will start coming back up. I know that to have been true in some cases, and will all of the research, and we are going to put almost $70 million into it this year, we still have nothing but counseling, AAA, and Antabuse. Is that correct? We have not produced much in the past 14 years, then, in this area, have we?

Mr. **Kefauver.** I think there is considerable increase in the basic knowledge of not only alcoholism but specific therapies.

Mr. **Carter.** My goodness. What has become of that money? Sixty million to $70 million spent per year for research, and a mountain has labored and dropped forth a mouse, Doctor. Let's look at this. Of course, you are divided, your mental health groups are divided into regions, and in those regions portions treat alcoholism and drug abuse. Is that correct sir?

Mr. **Kefauver.** We do not operate alcoholism programs out of our regional offices, if that is what you are referring to.

Mr. **Carter.** No, no, but regions under the mental health program.

Mr. **Kefauver.** Yes.

Mr. **Carter.** Of which one in Kentucky is now bankrupt. Do you keep your fingers on those things pretty closely?

Mr. **Kefauver.** I think the reference you make is to a community mental health center.

Mr. **Carter.** This is the river region, yes, sir, and our alcoholism program is tied into that, and also your drug abuse program. I do not know whether it is doing much good or not. I have never observed much effect.

Mr. **Kefauver.** And I think we are preparing something.

Mr. **Carter.** I regret to say that, but we had better tell it like it is. Personally, I would like to see them become effective. Usually, we commit to those regions a certain number of hospitals or beds for treatment, but I have never seen them used, for some reason unknown to me.

Now, in cancer we are increasing the research effort, are we, or does it stay about the same?

Dr. **Fredrickson.** For 1979, Dr. Carter, the figure for the Cancer Institute is the same as the 1978 level.

Mr. **Carter.** You don't even account for the inflationary factor?

Dr. **Fredrickson.** No, sir, not in the 1979 administration budget.

Mr. **Carter.** Yes, sir. Describe some of the research that is going on now in the treatment of cancer, some of the different drugs that are used, and what you are finding out, please, sir. Dr. Upton?

Dr. UPTON. We are conducting clinical trials in more than 700 institutions involving more than 3,000 clinical investigators.

Mr. CARTER. Yes, sir.

Dr. UPTON. Our protocols involving cancers of various sites—breast, bowel, lung, head, neck, ovary, bladder, prostate.

Mr. CARTER. Yes, sir.

Dr. UPTON. The results of these experiments to date indicate that contrary to what one would have believed 20 to 30 years ago, with some types of cancer—disseminated cancer—long-term remissions can be elicited with drugs.

Mr. CARTER. What particular type of cancer and what particular type of drug?

Dr. UPTON. I am not a therapist, Dr. Carter.

Mr. CARTER. Yes, sir.

Dr. UPTON. So I am hesitant to review for you the specific protocols, although I would be happy to supply the information for the record.

Mr. CARTER. But you are the director of this institute?

Dr. UPTON. That is correct.

Mr. CARTER. What is your function, then, if you are not a therapist?

Dr. UPTON. I have devoted my career to carcinogenesis.

Mr. CARTER. Yes sir, how it starts.

Dr. UPTON. That is correct.

Mr. CARTER. The origin of it. What is the origin?

Dr. UPTON. We now see the development of cancer as a multicausal process, involving the interaction of genetic determinants which influence susceptibility and environmental factors. In some instances, heredity plays a predominant role, or would appear to play a predominant role. In other instances, the role of hereditary factors is yet to be identified.

We recognize in the environment a number of factors that can act on the system to increase risk—radiation, alkyllating agents, tobacco, and so on.

Mr. CARTER. I believe that it may be stated by a very prominent physician that radiation is the cause of 95 percent of our cancers. Would you agree with that?

Dr. UPTON. The suggestion that—Did you say radiation?

Mr. CARTER. Yes, sir.

Dr. UPTON. The suggestion that radiation might account for 95 percent seems to me to be exaggerated. The National Academy of Sciences Committee on the Biological Effects of Ionizing Radiation estimated that natural background radiation might account for 1 to 2 percent of the spontaneously occurring cases. It is hard for me, given what we know about different forms of radiation and the exposure of the population to radiation from manmade sources in addition to background, to arrive at a 95-percent estimate.

Mr. CARTER. Have you noticed an increased incidence of cancers in youngsters born with deformities, such as a cleft palate or a club foot?

Dr. UPTON. I am not aware of data linking those conditions. I am not aware of data connecting those particular anomalies to an increased risk of cancer in childhood. There are others which have been associated.

Mr. CARTER. Yes, sir. Have you noticed or do you have knowledge of any relationship between welding, such as electrical or acetylene welding, and cancer.

Dr. UPTON. Again, Dr. Carter, I must confess that I do not know that literature in detail. There has been evidence linking exposure to nickel and nickel fumes with cancer of the lung. I would suppose in welding, depending upon the nature of the material being used, one would have a carcinogenic situation, but I am not aware of data that establish that association.

Mr. CARTER. Yes, sir. Nickel. Of course, there are many, many others.

Dr. UPTON. Cobalt and chromium for example.

Mr. CARTER. And there are many other elements. We find it in our uranium mines. There is a great increase.

Dr. UPTON. We attribute the increased risk in uranium miners to the inhaled radioactive gas in the mine, the radon.

Mr. CARTER. What progress have you made? How has your research helped in the treatment of cancer?

Dr. UPTON. As I mentioned a moment ago, we have seen evidence that for disseminated cancers of some types—for example, leukemias, lymphomas, and choriocarcinoma—we have long-term remissions which, in many instances, would appear tantamount to cures resulting from chemotherapy or drug administration. The research has shown that combinations of drugs are more effective than a single drug. In many instances, the periodicity of drug administration or the regimen of treatment is also important.

Until recently, we have not sought to apply intensive early adjuvant chemotherapy to the more common solid tumors of adults, the expectation being that if we could detect them when they are localized, and remove them surgically, and/or irridiate the tumor site, the outlook would be favorable. That can be the case, of course, when the tumor is detected early enough.

Research has shown that in all too many instances, however, even though the tumor appears localized at the time of detection, cells have disseminated from the tumor site and invaded other parts of the body. In those instances it would appear now from trials in progress that adjuvant chemotherapy can greatly improve survival. We have seen this in pre-menopausal women treated for carcinoma of the breast. We have seen it with oat cell carcinoma of the lung and with osteogenic sarcoma, so I think we are now seeing preliminary indications that some of the dramatic gains achieved heretofore primarily with the leukemias and lymphomas may indeed be possible with the more common solid tumors of adult life.

Mr. CARTER. Is it not true that many of the medicines used in chemotherapy are carcinogenic themselves?

Dr. UPTON. That would appear to be the case, unfortunately. Experiments in animals have shown that they are radiomimetic in the sense that they are carcinogenic, and there is now epidemiological evidence in the followup of patients who have survived, thanks to chemotherapy and radiation, of an increased risk of a second cancer.

We see here an unfortunate type of side effect. One of the efforts going on in our division of cancer treatment is to analyze the carcinogenicity of anticancer agents, in an effort to select, if possible, agents effective in the treatment of cancer which at the same time are not themselves carcinogenic.

Mr. Carter. So this goes really not only with chemotherapy but also X-ray therapy.

Dr. Upton. Indeed it does. Yes, sir.

Mr. Carter. The cure may cause another cancer, in other words.

Mr. Maguire. Is the gentleman moving towards the conclusion of his questions? How much time would he like from the chair? The chair wants to be generous, but to raise the question in any case.

Mr. Carter. I guess I will conclude as of now. Thank you very kindly. You know of my extreme interest in the area.

Mr. Maguire. Well, why do you not conclude with a rather generous allocation of time?

Mr. Carter. Thank you, sir. I have had my time, I suppose.

Mr. Maguire. The gentleman has had about 20 minutes.

Let me ask a couple of questions, and perhaps we can return for any final questions.

Mr. Carter. Thank you. Good day.

Mr. Maguire. I am sorry the gentleman is discomforted.

With respect to the allocation of funds for prevention, is it possible for you to give us some figures about what exactly is being spent and on what separate categories under the heading of preventive strategies?

Dr. Fredrickson. For cancer, Mr. Maguire?

Dr. Upton. I would be happy to supply those for the record, Mr. Chairman.

Mr. Maguire. All right, if you would.

[Testimony resumes on page 82.]

[The following information was received for the record:]

CANCER PREVENTION

For purposes of this presentation, prevention is classified as both primary and secondary and is further refined as follows:

1. Primary Prevention -- that research which is aimed at development of interventions to be employed before the biologic onset of disease, including research and education directed at changing behavior in such a way that disease will be averted or ameliorated.

2. Secondary Prevention -- research directed toward interventions after the disease can be detected, but before it is symtomatic or recognized, as well as research aimed in preventing further progress of already-established disease.

Primary Prevention Activities

The National Cancer Institute has spent, in fiscal year 1977, a total of $230,757,000 for primary cancer prevention activities. Programmatically, this breaks down as follows:

	FY-1977
Research:	
Epidemiology	$22,627,000
Carcinogenesis (Physical & Chemical)	93,149,000
Viral Oncology	95,734,000
Nutrition	4,027,000
Immunology	6,151,000
Total Research	$221,688,000
Cancer Control:	9,069,000
Total Primary Prevention	$230,757,000

A complete description of all of NCI's primary prevention activities is contained in the following detailed paper, entitled "Cancer Prevention Program":

CANCER PREVENTION PROGRAM

NATIONAL CANCER INSTITUTE

Prevention offers the best hope for ultimate control of cancer. Hence, research on cancer prevention occupies a high priority in the programs of the National Cancer Institute.

Research on the causes and prevention of cancer, one of four major research thrusts of the National Cancer Institute, seeks to identify factors that cause cancer in man, and to develop mechanisms for cancer prevention. The research efforts include, first, studies of known carcinogens, such as radiation (including ultraviolet light), tobacco, and chemicals such as drugs and hormones. Second, we are screening for new cancer-causing chemicals by long-term animal testing and short-term methods; and are also emphasizing research to improve these testing procedures. Third, we are conducting and supporting studies to identify patterns of the occurrence of cancer in our population as it relates to the environment. Fourth, we support research on the basic mechanisms of how normal cells become cancerous. Other research efforts include studies of the role of viruses, studies of the role of nutrition and susceptibility to cancer, and development of less hazardous cigarettes, to help those who have not been able to stop smoking reduce their risk of developing lung and other types of cancer.

Demonstration and educational programs are also an important part of NCI activities in cancer prevention. Efforts directed toward the health professions and the public have increased the awareness of cancer risks associated with radiation, tobacco, asbestos, vinyl chloride and the drug, estrogen. We believe that these activities have facilitated steps to lower risks and thus to prevent cancers that might otherwise have been induced.

Environmental Factors and Cancer

Research on the involvement of environmental factors in the occurrence of cancer includes not only air and water, but also food, drink, smoking, drugs, workplace, home, sunlight, and other aspects of personal lifestyles. Chemicals and radiations are certainly involved, and there is also a possible causative role for viruses.

One persuasive line of evidence is based on studies of cancer incidence in different regions of the world. Incidence of cancer of any given type can vary by a factor of 2,000 percent or more. If the rate of each type of cancer in all parts of the world were reduced to that of the region with the lowest incidence for each type, the overall frequency for all types combined could be reduced by as much as 80 to 90 percent. Further, in migrant populations, the incidence of a given type of cancer tends to change to the incidence characteristic of that type in the adopted region. Thus, the evidence implies that environmental factors play a major role in the causation of cancer, responsible, perhaps, for 80 to 90 percent of the total incidence of the disease.

There is general agreement that cigarette smoking contributes to about 40 percent of cancers in men in the United States. The contribution of smoking to cancer in women, although lower, is rising. This large segment of the cancer burden consists mainly of lung cancer, but includes also cancers of the throat, esophagus, bladder, and pancreas.

Known chemical carcinogens are estimated to account for a maximum of 10 percent of cancers in men. These include cancers related to tobacco plus alcohol use and/or occupational exposures such as asbestos, vinyl chloride, benzene, beta-naphthylamine, and petroleum residues. Sunlight, X-rays, and other forms of radiation may cause another five percent.

The action of environmental factors is thought to be conditioned by an individual's susceptibility. Many scientists believe that environmental factors--chemicals, radiations, and possibly viruses, all playing a role in one or another instance--interact with hereditary information in cells to produce a complex sequence of events that lead to development of cancer.

Thus, most cancers are theoretically preventable, if we identify causative agents, and avoid them, eliminate them from the environment, or modify the individual's response to them, to reverse or arrest the biological effects that may result in cancer. Extensive research is needed before it will be possible to prescribe practical steps for preventing the cancer-causing action of environmental factors.

Chemicals are thought to play a major role in cancer incidence. Among the vast numbers of potentially carcinogenic chemicals in the environment, relatively few have been demonstrated to date to cause human cancer. Estimates of the number of chemicals in the world exceed 7,000,000 and the Chemical Abstracts Registry now lists 4,500,000 different entries. Relatively few chemicals have been tested for carcinogenicity in animals. Some 16,000 reports of animal experiments of various sorts have been published. Most of them are not definitive, but some evidence of carcinogenicity has been established in animals for about 400 chemicals.

Some 30 to 35 chemicals, depending on the criteria used, have been established as carcinogenic for human populations. Noteworthy examples include tobacco smoke, industrial chemicals, asbestos, such drugs as DES, and radiations. The chemicals that are carcinogenic for man are also carcinogenic for animals with two exceptions--arsenic and benzene, which, we believe, have not yet been adequately tested in animals.

More than 30,000 chemicals are estimated to have commercial importance. In addition, some 700 new chemicals are introduced into commerce each year. Thus, a vastly increased number of chemicals may ultimately prove capable of exerting carcinogenic effects in humans. Because cancer often takes 10 to 20 to 30 years to develop, it is conceivable that the carcinogenic effects of current exposure to the increasing numbers of environmental chemicals may not become evident for some years.

Bioassay Program

Because the carcinogenicity of the chemicals in man correlates well with their carcinogenicity in animals, it is reasonable to identify presumptive human carcinogens through animal experiments. Chemical testing by the NCI began as a research effort and was expanded to its current level largely as a demonstration and feasibility study to develop means to fill the perceived Federal needs.

At present, approximately 90 chemicals are being tested in animals. Experiments on an additional 64 chemicals are being analyzed and reports are being prepared. Another 100 chemicals will be started on test this year. The testing is managed and directly supervised by the National Cancer Institute with support from a prime contractor, Tracor Jitco.

Our bioassay screening system consists of administration of a single chemical at two dose levels to rodents of two species in both sexes. Rodent species are used for the screening process because of their relatively short lifespans, their well-understood biological behavior, and the high rate of correlation between rodent carcinogenicity and the small number of known human carcinogens. In the interest of testing as large a number of chemicals as is economically feasible, a given chemical usually is given to only 50 animals of each sex and species at each dose level. Because of the small number of animals tested and their brief lifetimes as compared with that of humans, one of the dose levels is set as high as possible to maximize the chance that a carcinogen will not be undetected.

For this same reason, the route of administration for the chemical is selected to permit exposure of as many body organs as possible. Each animal test requires about four years, including design, administration of the chemical, and analysis of the results.

Because of the cost of these experiments both in time and dollars, selection of chemicals is a critical part of the testing process. At the present time, selection depends on information concerning extent of human exposure as well as the biological effects of a given chemical and any other similar chemical. Production data, information on dispersion into the environment, chemical structure, and mutagenicity data, for example, are examined by a Chemical Selection Working Group composed of scientists from NCI and 10 other Federal agencies. This group nominates chemicals for testing. Their nominations go to a chemical selection subgroup of the NCI Clearinghouse on Environmental Carcinogens, a chartered advisory body of non-government members that meets in open session to make recommendations to NCI. Additional information on chemicals selected for testing is received by the National Cancer Institute as a result of these discussions, and the final decision to test is made by NCI staff.

Similar review procedures with other Clearinghouse Subgroups concerned with experimental design and data evaluation provide review of the testing protocol and results. After review, the National Cancer Institute publishes a report of the findings, announced in the Federal register, and informs the public through the media.

Copies of the report are sent to other Federal agencies. Additional information on some chemicals is also sent to physicians concerned with occupational medicine, industrial and labor organizations, and environmental and consumer groups.

Each animal experiment costs about $300,000. Together with limited laboratory facilities and a shortage of personnel trained to conduct animal tests for carcinogenicity, the Nation's capacity for carcinogenesis testing is severely limited. The presently available resources for carcinogenesis testing in the world are estimated to permit testing of 200 to 500 chemicals per year.

We are keenly aware that our present bioassay techniques must be considered limited in their predictive value. Much uncertainty exists in extrapolating across species. Improved knowledge of species similarities and differences is needed, as is better understanding of the correlation between in vitro and in vivo tests. To predict the risk to man from known animal carcinogens, it is necessary to have information on the dose levels that are carcinogenic, the relative potency of the carcinogen, the routes of exposure to which man is susceptible, and the relative ability of human tissues to detoxify, metabolize, and excrete carcinogens.

Moreover, human populations are rarely exposed to large doses of single carcinogens. Instead, man usually is exposed intermittently to many carcinogens in various combinations and at low doses. Two or more carcinogens acting in combination may be mutually inhibitory, additive, or multiplicative in their effects. This reflects in part the fact that there are different kinds of carcinogens, some of which act largely to promote the cancer inducing effects of others.

A further problem arises from the evidence that implies that cancer is a multi-stage process, in which successive stages may be influenced in different ways by various types of carcinogenic and anticarcinogenic stimuli. At present, our knowledge is inadequate to characterize the status and outlook of a given precancerous condition or to define the probable net effect of a particular carcinogenic or anticarcinogenic stimulus in a given individual.

Thus, the NCI current animal bioassay effort for chemical carcinogens can detect only the potential of a chemical for causing cancer in humans. Its results cannot predict whether a particular chemical will cause human cancer, but may serve as a basis for further studies of the chemical in question.

Extensive research is in progress to improve test procedures and to learn more about the factors that influence cancer induction, such as dose, age, sex, route of exposure, and the effects of mixtures of chemicals. The goal is to develop more sensitive, reliable, and cost-effective long-term animal tests, and short-term, inexpensive, laboratory techniques. Emphasis in the long-term tests will be placed on selection of sensitive animal species and strains, route of exposure, and measuring the amount of chemical entering the tissues of the test animal.

Short-term assays under study include those in which there is 1) induction of transformation of mammalian cells in culture; 2) mutagenic or cytogenetic changes in microorganisms or mammalian cells; and 3) interactions between chemicals and cellular DNA. It is anticipated that some short-term tests may substitute for long-term animal tests, while others may be useful in pretest screening to decrease the number of chemicals that have to be tested in animals. Short-term tests also have a potential for enhancing the effectiveness of screening the environment as well as specimens from the body, such as tissues and fluids, for potentially carcinogenic substances. One short-term test, the Ames test, which assays for mutagenicity of chemicals in bacteria, is being used to assist in the selection and ranking of chemicals for animal testing, and to provide information about the biological potential of environmental chemicals.

In other activities, the carcinogenesis information system will be further developed to collect, analyze, and disseminate data on human exposure to chemicals and toxicity of environmental chemicals, and provide a management system to aid in conducting and monitoring of animal experiments in contractor laboratories. Studies will be conducted to develop satisfactory methods to test mixtures of chemicals more representative of those to which human populations are exposed under natural conditions. Studies will include co-carcinogens and promoters, chemicals that by themselves may not produce cancer, but act together with small amounts of carcinogens to cause cancer.

Collaboration With Other Federal Agencies

The National Cancer Institute has come to be relied on as the primary source of information for regulatory agencies. We have identified a growing number of agents carcinogenic for animals, thus pointing to possible sources of risk for human populations.

For example, the Environmental Protection Agency (EPA) issued regulations on the use of the pesticides chlordane and heptachlor, based on information made available by NCI. The Occupational Safety and Health Administration (OSHA) modified the standard for occupational exposure to trichloroethylene. The Food and Drug Administration (FDA) banned the use of chloroform in drugs and cosmetics, including toothpaste. FDA requested the National Cancer Institute to review the scientific evidence on the carcinogenicity of cyclamate, an artificial sweetener. On the basis of our information, the FDA ruled that the safety of the artificial sweetener is too uncertain to allow it back on the market and refused to lift the ban, which had been ordered in 1969. The action taken by the Consumer Product Safety Commission (CPSC) banning the use of the flame retardant TRIS in children's sleepwear was based on results from our test program showing it to be carcinogenic in rodents.

In the last several years, NCI has expanded its collaborative efforts with other concerned Federal agencies to assist them in their responsibilities for regulatory actions and further studies of suspected substances. In the past few months, the NCI and FDA have been working together to plan an epidemiological study of saccharin, another artificial sweetener, and other substances in relation to the development of bladder cancer. We have collaborated with the EPA in carcinogenesis studies in biorefractories in municipal water supplies, and are conducting activities involved with EPA's responsibilities under the Toxic Substances Control Act. NCI has a staff member as a representative on the EPA Science Advisory Board. NCI has an interagency agreement with OSHA for an occupational cancer information and alert program to make available information and training aimed at reducing the risk of cancer among workers of the country. NCI has transferred funds to the National Institute for Occupational Safety and Health (NIOSH) for some 20 projects, primarily epidemiological studies in occupational situations. Together NCI and NIOSH have decided on the projects for using the funds. We have an interagency agreement with FDA's Bureau of Radiological Health to develop monitoring and technical assistance programs through State health departments for the radiation dosage for mammography examinations.

The National Cancer Institute has organized a Clearinghouse on Environmental Carcinogens, consisting of 35 non-government individuals drawn from academic, medical and scientific research institutions as well as from industry, organized labor and public interest groups. Representatives of various Federal agencies concerned with environmental causes of cancer also participate in Clearinghouse activities. Its functions include selection of chemicals that are suspect, designing experiments to determine whether or not they are carcinogens, data evaluation and risk assessment.

Another relevant NCI committee is the Interagency Collaborative Group on Environmental Carcinogenesis. It serves as a mechanism for developing and disseminating information and data from Federal, State, and industrial organizations, and has continuous contacts with industry, trade associations, and labor unions. Agency or subagency representation includes 29 agencies and 51 representatives. Meeting at six-week intervals, this group serves as a focal point for interchange in programs relating to air pollution, water quality, and diet contaminants.

Among the agencies of the Department of Health, Education, and Welfare, chemical testing efforts are conducted by the Food and Drug Administration, the National Institute for Occupational Safety and Health, the National Institute of Environmental Health Sciences, and the National Cancer Institute. The NCI studies constitute the majority of these. It is noteworthy in this connection that cancer is only one of the health impacts of chemical exposure. The state-of-the-art for testing other long-term health effects is as limited as the testing for cancer-causing effects.

NIEHS has a growing interest in the development of test methods for mutagenicity and teratogenicity, as well as for other toxicity indicators. NCI and NIEHS are cooperating in the development of a program aimed at testing the animals in the cancer bioassay program for other toxicities. When fully operational, this will greatly increase the benefit derived from the NCI bioassay program. Thus, to a significant degree, the NCI and NIEHS are embarked on an extension of testing, from carcinogenicity to a whole range of toxic effects.

We believe that the role of the Federal government will change over the next decade from one of providing major support for chronic toxicity testing to one of primary concern with the development and validation of new test methods and quality control of testing conducted by industry. During the interim, the regulatory agencies will continue to rely heavily on NCI and other research agencies for support in environmental toxicology. The four principal regulatory agencies, FDA, EPA, CPSC, and OSHA have recently formed an Interagency Regulatory Agency Liaison Group for the purpose of coordinating and pooling their resources and activities in environmental toxicology. They have made overtures to NCI, NIEHS, and NIOSH to join them in a common approach to problems of mutual interest.

Although over the long run, adequate testing of chemicals may be done by industry to enable regulation prior to their introduction into commerce, a major concern now is that allocating resources to expand the NCI testing program may occur at the expense of research needed to improve testing methods. It is important that the role of the NCI--and HEW--in chemical testing be critically examined within the context of the needs and responsibilities of the various regulatory agencies.

Epidemiological Studies

Epidemiological studies (statistical studies) have provided new clues to environmental risk factors through the identification of high-risk groups, opening possible avenues to cancer prevention. One such study has produced atlases of cancer mortality among United States whites and non-whites in which are detailed the relationship between geography and death-rate patterns for different types of cancer. Comparison of the data for non-whites and whites has shown similarities in death-rate patterns for several types of cancer. These similarities imply a role of environmental factors in their causation.

An unexpectedly high risk of lung cancer was found in southern coastal counties of the United States. The possibility that this might be due to exposure to carcinogens in certain occupations, such as exposure to asbestos in shipbuilding, led the National Cancer Institute to conduct an interview analysis currently being completed, of areas along the Eastern and Louisiana-Florida seacoasts. The NCI has planned an analysis of the cancer death experience of shipyard workers who have worked in the State of Virginia, as well as an interview study of next of kin of shipyard workers. Both of these studies should be completed by the summer of 1978. As an outgrowth, the NCI will assist in expanded efforts to alert shipyard workers and former shipyard workers to the possible hazards of asbestos exposure is under development.

Other occupation-related epidemiological studies to obtain clues to cancer risks include studies of workers in leather, petrochemical, auto, pharmaceutical, and dry cleaning industries. Studies of the risk of colon cancer highlighted by the death-rate patterns in Nebraska will be completed in 1979, and the cooperative study of bladder cancer now getting under way in collaboration with the FDA also will be completed in 1979. Studies are in progress to evaluate risks of drug-induced cancer among patients receiving drugs for the treatment of various cancers, for the suppression of the immune system following transplantation, and for the treatment of menopause.

Ongoing studies of the risks of radiation-induced cancer will continue to evaluate the risk of breast cancer for women exposed to fluoroscopy and for Japanese women who survived the 1945 atomic bomb explosions. Children who received radioactive iodine as part of thyroid diagnostic tests will be followed. Studies of cancer-prone families are in progress in an effort to clarify the role of genetics in the development of cancer.

Research on the Process of Carcinogenesis

Research on the processes by which a normal cell is transformed to a cancer cell and a cancer cell develops into a cancerous growth is an important part of the cancer prevention program of the National Cancer Institute. Such basic knowledge is necessary for the development of approaches to cancer prevention.

Studies of how carcinogens are metabolized in the body provide information to explain the differing responses of various species to carcinogens. In addition, metabolic studies help to identify activated forms of such compounds and the products of their reaction with the large molecules of cells. Because the development of cancer is viewed as a stepwise process, studies of the process of carcinogenesis involve analysis of the changes in cells exposed to carcinogens, along with the metabolic reactions of carcinogenic chemicals within cells. An inherent potential for prevention exists in this stepwise process, in that inhibition of the process conceivably may be introduced at any level. For example, studies of the mechanism of conversion of the widely occurring carcinogen, benz(a)pyrene, suggest that a highly reactive epoxide derivative may be the carcinogenic form of benz(a)pyrene in the metabolic pathway.

Enzymes involved in the activation pathways and the deactivation of carcinogens are studied, as well as other factors such as hormones, nutritional status, and genetic background, which determine the levels of these enzymes. Such information may help in the development of methods of blocking the activation processes, and thus reduce the effect of carcinogens.

A clinical trial in cancer prevention is about to be launched as a result of findings in laboratory studies. Scientists observed that vitamin A-like substances could reverse the action of known cancer-causing substances in tests on laboratory animals, and thus prevent the development of cancer. NCI will support a clinical trial of 13-_cis_-retinoic acid, a chemical relative of vitamin A, to test the value of the compound in preventing or delaying the onset of bladder cancer in persons with precancerous bladder lesions. If this trial is successful, the principle could be adapted to other persons at high risk of epithelial cancers, since bladder cancer is an epithelial cancer.

Other possible cancer-preventive agents called antioxidants have been discovered in work with laboratory animals. These will undergo evaluation and further animal testing. Immunology, the study of the immune system which protects the body against disease, is being investigated for its possible role in the development of means to prevent cancer.

Virus Research

The number of identified virus-induced tumors in the laboratory has increased steadily from the mid-1950's until the present, as have the number of viruses with cancer-causing potential for almost every species of animal including sub-human primates. This is such a widespread phenomenon that, although no human cancer-causing viruses have been definitively identified so far, it seems likely that viruses ultimately will be found to be causative agents of some forms of cancer in man. In fact, the Epstein-Barr virus has recently been implicated in the etiology of a lymphoproliferative disease in subjects with a hereditary form of immunodeficiency. Thus, it has become evident, from this and other developments that cancer induction is sufficiently complex that identification of a virus alone may not provide the complete answer to its role in the causation of cancer.

We now know that a tumor virus contains genetic materials that integrate with the hereditary materials of the cell, and cause changes that transform the cells to malignancy. The process may be activated by radiation, chemicals, and other environmental agents.

The emphasis in cancer virology has moved from the search for viruses to studies of ways of controlling the expression of viral genes. The direction of protein synthesis by specific genes (the basic units of heredity) is called the "expression" of those genes. Virologists studying cells at the molecular level have discovered that the production of complete virus particles is not required for cancer formation by viruses. Even the presence of the whole viral genome (the nucleic acid core of the virus) is not necessary for malignant conversion. In all tumor viruses studied, the transforming information is contained in one gene or a small number of genes that can be expressed in the absence of other viral functions. It appears that one gene, producing one product, can specifically transform a target cell to malignancy. The identification of the product of this gene and the study of its mechanism of action are major thrusts of cancer virology at this time.

Smoking and Health

A continuing problem in cancer prevention is smoking. Many studies have shown that a reduction of exposure to tobacco smoke should result in reduced incidence of smoking-related cancers and other diseases. It is best not to smoke. However, for those unable to stop smoking, the best policy at present is to smoke less hazardous cigarettes.

The National Cancer Institute has supported a program to develop a less hazardous cigarette. This program has produced cigarettes containing fewer than 10 milligrams of tar and less than 1 milligram of nicotine per cigarette. These figures compare well with the 19.2 milligrams of tar and 1.3 milligrams of nicotine for the usual cigarettes manufactured in the United States today. Less hazardous cigarettes are in wide use, and it is hoped they will reduce the risk of developing lung and other cancers.

Also helping to reduce tar content for smokers is the addition of filters which strain out a good deal of the tar. Today, 87 percent of all cigarettes have filters. The tar content of cigarettes is also reduced by adding synthetic products, which have very little tar, and also, by increasing the bulk of the tobacco, and therefore incorporating less actual tobacco per cigarette.

The National Cancer Institute collaborates in its smoking and health program with the Office of the Assistant Secretary for Health, HEW; the National Heart, Lung and Blood Institute of NIH; Bureau of Health Education of the Center for Disease Control; Department of Agriculture; American Cancer Society; other research and public health agencies; and the tobacco industry. The efforts are directed toward identifying and modifying the behavior of individuals most likely to develop smoking-related cancers, modifying smoking products, and developing drugs to help high-risk individuals stop smoking or reduce the hazardous effects of smoking.

The effectiveness of controlling lung cancer through prevention efforts was illustrated by a 30 percent reduction of deaths among British male physicians during the period 1954 to 1964 when many stopped smoking, compared with a 25 percent increase among all men in England and Wales who persisted in smoking during the same time period.

New information has emerged from recent National surveys of the smoking habits of adults, teenagers, and health professionals. They show definite trends, such as in increase in smoking among teenage girls, and a reduction in smoking among adults in general and among health professionals. This information is being used for prevention programs to educate the American public to stop smoking or at least to accept less hazardous cigarettes and limited cigarette consumption.

The National Cancer Institute has several activities ongoing. One is to develop educational units designed to inform and motivate public, patient, and professional audiences on the latest information about smoking and cancer obtained from the National surveys. The units will be distributed through intermediary groups having direct access to specific audiences. In this connection, a comprehensive description of information in a number of areas relating to smoking was summarized in a publication "The Smoking Digest." The purpose of the publication is to provide a resource for health planners containing the most recent information about cigarette smokers, biomedical effects of cigarette smoking, cessation techniques and programs, and smoking legislation and regulation.

Other activities involve the support of a school-based smoking prevention program directed toward children in grades 5 to 9 and a program for training teachers. Another project is supporting an educational program designed for workers exposed to high levels of asbestos, because smoking has been shown to augment the hazard of occupational exposure to asbestos.

Diet and Nutrition

In response to a Congressional mandate, the National Cancer Institute is developing a major program in diet, nutrition, and cancer to determine how control of certain dietary factors, including over-nutrition, may reduce the occurrence of cancer. (The program is also supporting research to increase appetite and food utilization in cancer patients, in order to maximize nutritional support during therapy and rehabilitation.)

An extensive amount of data relating nutrition to cancer is becoming available. In addition to the search for specific carcinogens that may play a causative role, nutritional deficiencies and/or excesses also are being studied for their role in contributing to the development of cancer. Present knowledge provides clues implicating such dietary factors as fat and meat intake, excess caloric intake, and nutritional habits that affect the hormonal and metabolic balances. Thus, there is a potential for cancer prevention and further research in this area.

The NCI has held a series of six workshops, in which approximately 60 experts developed some 50 proposals for research on the role of nutrition in cancer causation and treatment. In collaboration with two voluntary organizations, the American Cancer Society and the Candlelighters, practical dietary handbooks were prepared for the management of adult and pediatric cancer patients.

Education

An area of the National Cancer Institute environmental carcinogenesis program that has greatly increased in activity is education. In addition to the educational efforts mentioned in earlier pages of this report (in relation to smoking, asbestos, and the occupational cancer information and alert program), the NCI has other ongoing activities.

One is a prevention project for workers in Tyler, Texas exposed to asbestos, and another one for workers in Louisville, Kentucky, exposed to vinyl chloride, both proved carcinogenic substances. Medical surveillance and health education are provided to the workers and their families to assure early detection of precancerous lesions and early cancer. In addition, a smoking cessation program was implemented in order to enhance the opportunities for prevention of cancer in the Tyler, Texas workers.

Another project directed to a special population group is a followup study of 4,000 young women exposed before birth to diethylstilbestrol (DES) or other synthetic estrogens. The study should provide definitive answers regarding the risk to cancer or other abnormalities of the genital tract due to such exposure.

A conference was held in cooperation with the National Institute of Arthritis, Metabolism, and Digestive Diseases at NIH and the Bureau of Radiological Health of the Food and Drug Administration to assess the state of knowledge of the late effects of irradiation to the head and neck in infancy and childhood, and to develop guidelines for practicing physicians concerning the risks for thyroid cancer among thousands of people who received such irradiation.

Brochures were published to provide information for physicians and the public concerning irradiation-related thyroid cancer and the effects of DES exposure among daughters of mothers who received the drug during pregnancy. Educational programs are being developed to provide information to physicians through National and State medical organizations and health agencies, and to the public. Efforts are being developed to use the media to encourage possible high-risk persons to be screened.

Another avenue for conveying information to health practitioners and the public is the Cancer Information Service (CIS). Based in most of the Comprehensive Cancer Centers, CIS offices offer toll-free telephone service to accommodate cancer-related inquiries. Since the first office opened in February 1976, CIS offices have received nearly 100,000 calls from patients, individuals with symptoms, or their families. To back up the regional system, the NCI operates a National toll-free incoming telephone line.

Suggestions for Reducing Cancer Risk

In conclusion, the information about causes of cancer available at present permits some suggestions for preventive measures for individuals, to help reduce their risk of cancer. These include actions such as: Avoid smoking; avoid overexposure to the sun; be careful of the diet, avoiding excess caloric intake and decreasing quantity of smoked and fatty foods; avoid as much as possible exposure to car fumes, factory exhausts, household solvent cleaners, and garden and lawn chemicals; and avoid needless X-rays.

Secondary Prevention Activities

For activities which are considered secondary in prevention, a total of $56,185,000 was obligated in fiscal year 1977. This breakdown is as follows:

	1977
Control and Detection of Cancer	$23,247,000
Detection/Diagnosis Research	4,300,000
Cancer Diagnosis by Site	11,688,000
Tumor Biology	16,950,000
Total Secondary	$56,185,000
Total Primary & Secondary Prevention	$286,942,000

Activities in secondary prevention fall into three major classes, which are referred to as control and detection of cancer, general cancer diagnosis, and immuno-diagnosis. Under control and detection of cancer, efforts focus on the utilization of existing diagnostic techniques for the earliest possible diagnosis of disease. This involves principally screening, demonstration, and educational projects. Under general diagnosis, most efforts are directed at the development or improvement of diagnostic techniques which lead to the detection of cancer at the earliest possible stage of its development.

1. Control and Detection of Cancer

The National Cancer Institute, through the Division of Cancer Control and Rehabilitation, conducts a number of projects, the goal of which is the reduction or morbidity and mortality from all forms of cancer through the early detection of disease before metastases have occurred. Prompt diagnostic workup and thorough pretreatment evaluation enables the administration of the most appropriate therapeutic regimens at a time when treatment has the highest possibility of success. Current efforts and resources in this area have focused on detection and diagnosis of breast cancer, female pelvic cancer, and melanoma.

2. Detection/Diagnosis Research

The secondary prevention portion of this program includes better methods for definitive diagnosis of cancer at the earliest possible stage so treatment procedures have a better chance of success. This includes research for the evaluation and improvement of known diagnostic procedures as well as developing new definitive diagnostic methods. Of particular importance is the development of non-invasive procedures such as thermography and ultrasound.

3. Cancer Diagnosis by Site

Studies are underway to detect precancerous lesions in three major sites -- lung, pancreas and gastrointestinal tract.

Lung Cancer

A joint study currently is in progress by a Cooperative Early Lung Cancer Group. In this study each of three projects (at Mayo Foundation, Johns Hopkins University Medical School and Memorial Hospital-Strang Clinic in New York City) will screen at least 5,000 persons who are heavy smokers annually for lung cancer with frequent sputum cytology and chest x-ray examinations. In each project 5,000 other screenees (of equal risk) will be randomly selected to act as a control cohort. Localization of lesions is accomplished with fiberoptic bronchoscopy. The goal is to detect lung cancer at a sufficiently early stage to permit its removal and cure by a surgical procedure that will be less extensive than a pneumonectomy. The University of Cincinnati Statistical Center coordinates accumulation of data from the three cooperating projects. A Manual of Procedures has been compiled by the group. Ten thousand persons have already been screened at the Mayo Clinic, approximately 8,125 persons at the Johns Hopkins Medical School and 6,600 at Memorial Hospital. At Johns Hopkins Medical School studies continue on cytogenetics of lung cancer cells in sputum, immunological procedures in the detection of lung cancer and other procedures. The Mayo Clinic is studying the role of aryl hydrocarbon hydroxylase enzyme in heavy smokers and persons with lung cancer. At Memorial Hospital in New York City, studies toward the development of a squamous cell antigen related to lung cancer will be undertaken.

Cancer of the Pancreas

Three cooperating institutions, Mayo Foundation, the University of Chicago and Memorial Hospital-Sloan Kettering Institute, are studying, in a predetermined manner by a common protocol, patients who are suspected of having cancer of the pancreas and are about to undergo abdominal surgery. Special studies delineated in the protocol include preoperative and operative study of CEA in peripheral and portal venous blood. Special studies are being made of pancreatic excretions obtained through a fiberoptic scope in the duodenum, pancreatic and biliary ducts. Such secretions are being studied for tumor-associated antigens, abnormal enzyme content, biochemical alterations, as well as cytological changes which will permit the earlier diagnosis of pancreatic cancer. Other diagnostic methods being investigated include imaging with ultrasound, CTT scanning, radionuclides, and retrograde pancreatoduodenography.

Gastrointestinal Cancer

Several ongoing projects are concerned with various aspects of diagnosis of gastrointestinal cancer. Studies at University of Rochester and at eight other institutions under the auspices of the American College of Radiology are exploring methods of bowel preparation prior to barium enemas or colonscopy. At the Mayo Clinic, there is a study of carcinoembryonic antigen in conjunction with other tests for cancer to determine if any of these combinations will assist in the earlier diagnosis of gastrointestinal cancer. Two projects at Mt. Sinai Medical School and the University of Louisville, have been investigating development of a quick, sensitive method for the detection of human blood in stool specimens. A study at University of Minnesota will investigate the use of a screening technique for human blood in the stool as a means of detecting early bowel cancer and thereby possibly prolonging lives.

In addition to projects aimed at specific cancer sites, a variety of projects are aimed at improving technology toward secondary prevention. These include work on biological markers, nuclear magnetic resonance, and improved x-ray imaging, and improvement in methods of cytology automation. Another series of projects are directed toward improving the physical tools available for early diagnosis of breast cancer. In addition to mammography, these include xeromammography, ultrasound, electronic techniques, thermography and computerized tomography.

4. Tumor Biology

Approximately 25% of the Tumor Biology research program could be interpreted as supportive of research aimed at secondary prevention. The focus of this research in animal and cell culture model systems is directed toward an understanding of molecular and cellular processes where the development of intervention measures to prevent continued growth and spread of tumor cells are most likely to succeed. In addition, a substantial part of this effort is aimed at identifying potential diagnostic indicators for the early detection of the cancerous process. Specific major areas include:

- intracellular factors and factors in serum that contribute to and/or control tumor cell growth and DNA synthesis.

- identification of nutritional factors that are responsible for the maintenance of continued cell growth and metastasis.

- identification and characterization of tumor cell products that contribute to tumor progression or that may be useful in detection and diagnosis.

- identification of factors involved in cell adhesion, cell aggregation, and cell movement that contribute to metastasis.

- identification of metabolic abnormalities in tumor cells, especially in energy metabolism, that can be specifically interferred with to stem tumor growth.

The National Cancer Institute is obviously quite concerned with the importance of the utilization of prevention techniques to hasten the conquest of cancer. To this end, prevention activities range from attempts to reduce exposure to known carcinogens (cigarette smoking) to the search for yet unknown carcinogens (chemical testing, viruses). A variety of techniques are used, including the identification of persons at high risk, development of procedures for reducing exposure to cancer causing agents, assessment of most appropriate avoidance methods, development of techniques for follow-up on individuals already exposed, and promotion of resulting measures through educational and demonstration programs. Particular emphasis is being placed on identification of those carcinogenic agents that warrant specific prevention control activity. NCI has no regulatory authority over carcinogens either already in the environment or potential ones. Therefore, intervention techniques available to us are limited to those which relate to persuasion or through public and professional education. The smoking area constitutes the single greatest opportunity for cancer prevention. Nine of ten smokers indicate they would like to quit, according to latest behavioral data, and in the near future, the Institute's communications on smoking will be greatly increased. The emphasis will shift from the usual exhortation to stop smoking, to the provision of information on how to quit or where to obtain help in cessation. The National Cancer Institute supports information services that respond to about 150,000 public inquiries a year. Many of these are related to cancer prevention, specifically to immediate and specific hazards in the environment.

Mr. Maguire. There has been a lot of discussion about whether it is this percent, that percent or some other percent. There has been a lot of debate about it, and I guess there are a lot of different ways to make the calculations, but I think this committee would appreciate having whatever you can give us that you regard as accurate and properly identified as preventive.

Dr. Upton. The figures vary, of course, depending upon how one defines prevention—whether one speaks of primary prevention, secondary prevention, and so on. We can provide for the record a breakdown which will allow an understanding of how the figures are derived, and a further breakdown by the reader if different definitions are desired.

Mr. Maguire. Why do you not give us your best go at that? We would appreciate it.

Dr. Upton. I would be glad to. [See pp. 55–81.]

Mr. Maguire. In my earlier questioning, I had asked you whether it was your intention to expand and intensify your efforts in the area of cancer prevention. I do not think I got a specific response to that question. The inference was that you were going to, but I would like to hear you say you are going to if you are in fact going to, or that you are not going to if in fact you are not going to.

Dr. Upton. We are indeed going to. This is our highest priority at the present time.

Mr. Maguire. Thank you. Would you agree, Dr. Upton, that a great majority of human cancers are caused by environmental factors and are therefore preventable?

Dr. Upton. I would, Mr. Chairman. Yes.

Mr. Maguire. Dr. Fredrickson, would you agree with that as well?

Dr. Fredrickson. Yes, I would, Mr. Maguire.

Mr. Maguire. The committee does have a number of additional questions which are in written form which we would like to submit to you and invite your written responses to, and rather than take the time of the witnesses and the committee today, we will submit those questions.

Dr. Fredrickson. We would be very pleased to take care of them that way.

[Testimony resumes on p. 163.]

[The following questions and answers were submitted for the record:]

Responses to Questions from Members of the House Subcommittee on Health and the Environment for the Hearing Record

I. National Library of Medicine Medical Library Assistance Program

A. Would the National Library of Medicine be an appropriate repository for the establishment of a registry or integrated national data base to assist in the location of persons exposed to carcinogens and referral of these persons to appropriate health agencies and to facilitate studies of the effects of suspected carcinogenic substances on humans?

answer: The National Library of Medicine would not in our judgment be an appropriate repository for such a registry or integrated national data base. The data bases built and maintained by the National Library of Medicine are derived primarily from the published medical and scientific literatures. These data bases are non-confidential in content and are available for access by all who need the information they contain.

Identifying persons who had been exposed to carcinogens would require access to personnel records -- such as employment records, hospital records etc. -- which come under the provisions of the Privacy Act and would involve the data base builder with the handling of confidential information. Referral of exposed persons "to appropriate health agencies" would involve interactions with "patients" in the form of counseling. For these reasons these activities do not appear to be appropriate for the National Library of Medicine.

B. How many medical and health science libraries are there in the United States and how many of these receive assistance under the Medical Library Assistance Program?

answer: There are approximately 3000 medical and health science libraries in the United States with at least 500 bound volumes, 25 current journal subscriptions, and part or full-time staff. Of these, 1525 have received direct grant support under the Medical Library Assistance Program.

C. How many hospitals in the United States are (and how many are not) currently served by the regional and resource libraries supported by the Medical Library Assistance Program?

answer: Our data show that the 10 Regional Medical Libraries and their network of resource libraries are currently serving 3000 hospitals. The volume of interlibrary loan activity averages about 57 loans per year for each hospital. Approximately 4000 hospitals have not yet been reached.

D. How many individual and institutional training grants in the medical library sciences under Section 393 of the PHSA did the National Library of Medicine make in FY 1976 and FY 1977? What was the average and total monetary amount of these grants in FY 1976 and FY 1977?

answer: In FY 1976 thirteen institutional training grants were awarded in the total amount of $1,389,000 with an average per grant of $106,000. In FY 1977 ten were awarded for a total of $1,208,000 and an average of $120,000. Emphasis in both years was on the training of health professionals in the use of computer technology. Additionally one contract in the amount of $124,000 was awarded in FY 1977 to the Council on Library Resources to provide management internship training for medical librarians. The NLM did not make any individual training awards in 1976 or 1977.

II. National Cancer Institute

A. Comprehensive Cancer Centers

There are currently 19 comprehensive cancer centers receiving funding under a variety of legislative authorizations. The main funding mechanism for each of the comprehensive cancer centers is the Cancer Center Support (Core) Grant which is awarded under authority of Section 301 of the Public Health Service Act rather than Section 408 of the PHSA.

The total dollar support to individual centers and to the centers collectively is not available. However, in FY 1976 the National Cancer Institute awarded Cancer Center Support (Core) Grants to 61 centers for a total of $47.8 million. In FY 1977 there were 64 Cancer Center Support (Core) Grants made for a total of $55.1 million. Of these total grants, 19 were made to comprehensive cancer centers. In FY 1976, there was a total of $170.1 million in NCI funds awarded to institutions where comprehensive cancer centers are located. In FY 1977, this figure was $233.2 million. It should be emphasized that these awards were to the total institution, not necessarily restricted to the center. Other areas of support, such as funds from private foundations and other agencies of the Federal government enter into the total monetary funding picture for a comprehensive cancer center, but this information is not available to us.

The National Cancer Institute, in its requirements for recognition as a comprehensive cancer center, does require that comprehensive centers enter into community activity programs which fall into the category of "technology transfer programs."

The NCI does not require cancer centers to conduct cancer information programs for the public; however, through the Division of Cancer Control and Rehabilitation, there are cancer information systems available at most of the comprehensive cancer centers throughout the country.

There is no requirement on the part of the National Cancer Institute for a comprehensive cancer center to be involved in prevention per se. However, one of the characteristics for recognition as a comprehensive cancer center is to have an organized detection program, and all of the comprehensive cancer centers are in the process of developing such programs.

While the NCI has no requirement that a center should engage in activities involving children, a large number of the centers specialize in pediatric oncology, such as the Sidney Farber Cancer Institute, world renowned in this field.

The National Cancer Institute requires all comprehensive cancer centers to meet 10 criteria set forth by the National Cancer Advisory Board. These criteria are attached.

Since one of the criteria for recognition as a comprehensive cancer center is the conduct of basic research, all of the comprehensive cancer centers are involved to some degree in actual basic research.

The National Cancer Institute considers the centers, and more specifically the comprehensive cancer centers, to be a most important and integral part of the overall National Cancer Program.

Comprehensive Cancer Centers

Comprehensive Cancer Centers conduct long-term, multidisciplinary programs. The National Cancer Advisory Board has determined that Comprehensive Cancer Centers must have the following ten characteristics:

1. The center must have a stated purpose that includes carrying out of basic and clinical research, training, and demonstration of advanced diagnostic and treatment methods relating to cancer.
2. The center must have high quality interdisciplinary capability in the performance of diagnosis and treatment of malignant diseases.
3. The center must have an environment of excellence in basic science which will assure the highest quality in basic research.
4. The center should have or should develop an organized detection program.
5. The center must maintain a statistical base for evaluation of the results of its program activities. For this purpose, records should be developed which will standardize disease classification to enable exchange of information between institutions.
6. The center should provide leadership in developing community programs involving active participation by members of the medical profession practicing within the area served by the center.
7. The center must have a strong research base (fundamental and applied) and related training programs, with an organizational structure which will provide for the coordination of these activities with other facets of the center program.
8. The center will participate in the National Cancer Program by integrating its efforts with the activities of other centers in an integrated nationwide system for the prevention, diagnosis, and treatment of cancer. For this purpose, the center must have sufficient autonomy to facilitate this function.
9. The center must have an administrative structure that will assure maximum efficiency of operation and sound financial practices. The administration should include responsibility for program planning, monitoring, and execution as well as preparation of the budget and control of expenditures. Administration and management would include staff appointment and space allocation, the intent being that such a center will have the authority to establish the necessary administrative and management procedures for carrying out its total responsibility as defined in the criteria.
10. In order to give the program cohesion and identification, it is a requirement that each center identify an appropriate number of cancer center beds for interdisciplinary clinical research and treatment of inpatients. In general, it is expected that these will be grouped and that existing inpatient facilities will be committed for this purpose.

8. Please describe and indicate the number of and the total and average level of monetary support for community cancer programs supported by NCI in FY 1976 and FY 1977 under its cancer control program authority (section 409 of the PHSA). Please describe and provide comparable budgetary breakdowns for other programs supported under section 409. For FY 1976 and FY 1977, how many organizations and/or individuals have requested NCI funding to establish (1) community cancer programs, and (2) other programs supported under its section 409 authority? How many applications were submitted for funding of these programs? How many of these applications were approved and how many of these were funded? Would the cancer control program be more appropriately administered by a Federal agency other than NCI? Does the cancer control program represent an effective use of Federal funds?

Answer:

The number of and total and average level of monetary support for community cancer programs and for other programs supported by NCI under its Cancer Control authority in Fiscal Years 1976 and 1977 are as follows (amounts in thousands):

Program Area (Year)	No.	Amount	Average
FY 1976:			
Community Programs	73	$16,834	$231
Other Programs	169	$37,182	$220
FY 1977:			
Community Programs	82	$18,656	$228
Other Programs	154	$39,118	$254

It should be noted that a large number of awards categorized as "Other Programs" are heavily involved in activities at the community level.

The number of organizations and/or individuals requesting funding, the number approved, and the number funded are as follows:

Program Area (Year)	Applications	Approvals	Awards
FY 1976:			
Community Programs	82	74	73
Other Programs	303	182	169
FY 1977:			
Community Programs	121	83	82
Other Programs	235	162	154

It should be noted that these numbers include all non-competing renewals funding during the period in question.

Concerning the question, "Would the cancer control program be more appropriately administered by a Federal agency other than NCI?", the cancer control program is designed to provide a means by which the latest technological advances in the prevention and treatment of cancer can be transferred to those persons who can use those advances.

This transfer requires continuing scientific assessment to identify and evaluate technological advances which become candidates for transfer from research to medical practice. This requires a close association between the research and the control disciplines. For example, the readiness of candidate techniques for screening asymptomatic, high risk industrial workers for bladder cancer was recently evaluated by experts in cancer research and cancer control. While the techniques of detection were found to be effective and of minimal risk, there was insufficient evidence that early detection was of significant benefit in light of the treatment protocols presently available.

The process of assessment requires close and frequent contact between the control and the research components of the cancer program. The recently developed "matrix working group" within NCI help assure a constant interchange of information between the cancer research programs and the cancer control programs. A major administrative or geographic divorce of research and control programs would tend to constrict the flow of knowledge engendered by the frequent person to person contact.

Cancer control programs also require the mechanisms to transfer technology to the professional and to the public. In many cases these mechanisms are highly specific to cancer. For example, a significant part of the cancer control program is effected through major Cancer Centers which are devoted entirely to cancer research, treatment and education. An administrative separation of the Cancer Research Program and the Cancer Control Program would tend to complicate the relationships between the centers and the Federal cancer program. This relationship between research and control in the centers program is also true of other programs -- programs with the Clinical Cooperative Groups for example.

It is realized that other aspects of the cancer control program could potentially benefit from a closer association with other control programs. To develop these associations, NCI works closely with organizations such as OSHA, NIOSH, ...as well as with other Institutes within the NIH. It appears that these relationships can be strengthened and made more effective without any major organizational changes -- changes which might adversly affect the close symbiotic relationship between cancer research and cancer control.

The information which follows responds to the question posed as to whether or not Cancer Control activities represent an effective use of Federal funds.

A review of these information transfer processes that occurred by the end of FY 1977 through contractor and grantee activities shows that 1700 to 1800 community hospitals have been directly or indirectly involved in cancer control as a result of DCCR projects. This is over 42 percent of the 4000 community hospitals with 50 beds or more in the United States. The total Cancer Control Program has been established to influence the cancer care in target areas containing some 60 million people with information outreach available to an estimated 100 million persons in the United States.

In looking at how this occurred, Comprehensive Cancer Centers have, when including the activities made possible through DCCR's Clinical Oncology Program; Cancer Control in Clinical Cooperative groups; various Treatment Grants; Head and Neck Network Demonstration Program; Breast Cancer Network Demonstration Program, and Clinical Chemotherapy (leukemia and lymphoma) Network Demonstration Programs have involved some 590 community hospitals. The screening programs in the Cancer Control Program have involved some 84 additional community hospitals and over 800,000 persons who have received screening and cancer education. Projects to improve rehabilitation and continuing care interventions in the community setting through demonstrations and training programs have involved some 50 - 60 additional community hospitals as well as many other major centers that are hospitals experienced in cancer.

These estimates of involvement do not include those hospitals for which representatives from their staff attended one-of-a-kind project-sponsored activities such as workshops, training sessions, tumor board meetings, visitations, etc., in intervention programs where a routine communications was not being established for that particular event or activity. They do include the situations where a long range interaction is involved and/or where the training sessions were substantial in time required, and/or offered on a continuing basis. The occasional, one-of-a-kind interactions resulted in several thousand more professionals being influenced by the Cancer Control Program contractors and grantees. In total, it is estimated that over 30,000 professionals have been involved at some point in the Cancer Control Program to date.

C. Has the NCI completed its review of the 66 breast cancer cases of the cancer detection demonstration project alleged to have involved unnecessary surgery? If so, what are the results of this review, and what conclusions has NCI drawn respecting those allegations?

A final report has not yet been received from the Beahrs Group. From the supplementary report received in November 1977, the analysis of the so-called benign cases is as follows:

66 cases
- 2 cases computer mismatch
64 cases
-16 cases confirmed as cancer
48 cases
-11 cases biopsy only
37 cases

Of the 37 cases
-30 had two-stage surgery several days to several months after biopsy
7 cases done in a one-stage procedure (surgery same day as biopsy)

Of the 30 cases with two-stage operations, 15 had consultation by national experts, including members of the Pathology Working Group. The other 15 cases were reviewed on consultation by pathologists in the local community.

Of the seven cases with one-stage surgery, the project pathologist agreed with the diagnosis of cancer in two cases. In three cases the project pathologist disagreed with the hospital pathologist. In two cases, the diagnosis was based on frozen section slides, and no permanent slides were made.

There may be additional information available on these cases in the final Beahrs Group report.

X-ray mammography does not lead directly to breast surgery. Mammography examinations identify abnormalities in the breast. These may lead to recommendations for further diagnostic tests such as breast biopsy or breast aspiration. A biopsy or aspiration that confirms the diagnosis of cancer is usually the deciding factor on whether surgery is done. Modern mammography is detecting very small lesions (infiltrating cancers from 0.1 mm to 0.9 mm and all non-infiltrating cancers) in the female breast. These minimal cancers are difficult for pathologists to interpret, and there are differences of opinion among even expert breast pathologists on the exact classification of these disorders.

The surgeon when faced with making a decision regarding management of a breast condition must take into account many factors - the pathological report of cellular change being only one. Other factors include a personal history of breast cancer, family history of breast cancer, other possible risk factors, the degree of difficulty of evaluation of the breast tissue on physical examination or on mammograph due to the size of the breast or tissue consistency, the emotional state of the patient as well as the desire of the patient regarding the management of her problem.

D. What are the Department's views respecting statutory requirement that NCI conduct or contract for testing or other evaluation of the carcinogenicity and mutagenicity of substances, upon the request of the head of any other appropriate entity of the Executive or Legislative Branch of the U.S. Government, assuming that the other entity must reimburse NCI for the full cost of conducting or contracting for such testing or evaluation?

The potential adverse effects of some 30,000 or more chemicals of commercial importance in the nation are a grave and important concern. Identification of carcinogens among these compounds is perhaps the greatest concern, and much of the testing being done in this area is carried out by the National Cancer Institute. These tests cost up to $300,000 per compound, require extensive facilities and highly specialized personnel, and take three to six years to complete. Nonetheless, carcinogenesis may be only one of the effects of a given chemical. There are other toxic effects from chemicals, such as teratogenesis, fertility impairment, and other central nervous system diseases. Research now indicates that many of these can be determined through long-term animal tests, perhaps using a single test system, often identical to those employed to identify carcinogens.

Because of the similarities in such testing, it would be reasonable to consolidate much of the toxicity testing now conducted by NCI and NIEHS. A hierarchy of in vitro and in vivo tests could be employed in sequence. It would also lead to development of protocols designed to take advantage of the efficiency and economy of multiple end result testing. To realize such economies, the Directors of the NIH and the two institutes believe that, at a minimum, reorganization should consolidate the following resources into one Institute.

	Dollars (millions)	Man-Years
NCI	$ 21.9	56.5*
NIEHS	2.0	3.0
	$ 23.9	59.5

* HEW staff only; approximately an additional 260 man-years is provided by contractors.

The NIEHS with its broad mission could ideally accommodate such testing because of its concern over all disease end points. Plural governance of the testing would: (a) insure that NIH aresearch needs and the needs of the regulatory agencies are served, (b) provide policy direction for the testing, and (c) provide assistance in refining and explaining to the public the importance and meaning of tests results.

In addition to the NIH consolidation of efforts, the Department is exploring whether a consortial arrangement might be appropriate whereby resources of regulatory agencies could be added under some appropriate management designed to provide advisory and policy guidance and to insure that the needs of the regulatory agencies are served. Intense discussions are under way to determine these arrangements. It seems to us that the objectives of a statutory provision can be served better by one of the several plans being developed within DHEW, and with consultation with other regulatory agencies outside the Department.

E. What are the Department's views respecting a statutory requirement that at least two members of the National Cancer Advisory Board must be "community cancer care providers actively engaged in the treatment of cancer patients"?

Thepast and current composition of the National Cancer Advisory Board has and does include representatives actively engaged in the treatment of cancer patients. It is anticipated that future, routine appointments to the National Cancer Advisory Board will include individuals actively engaged in the treatment of cancer patients. Current Board members engaged in the treatment of cancer patients represent areas of surgery, radiology and chemotherapy. However, the Department has no objection to a statutory requirement that the membership of the National Cancer Advisory Board be modified to include additional members actively engaged in the treatment of cancer patients.

F. Please describe and provide budgetary information regarding the programs of the NCI relating to cancers which particularly afflict children.

After accidents, cancer is the most common killer of children. The annual rates, determined by the National Cancer Institute's Third National Cancer Survey, are 12.4/100,000 white and 9.8/100,000 black children under age 15 years, compared to 278 and 319/100,000 for all ages. In other words, of the approximately 600,000 new cases of cancer in the U.S. annually, only about 7,300 (1.2%) occur under age 15 years. However, the problem of childhood cancer may deserve proportionately greater effort than these figures suggest because of the large loss of person-years and the poignant unmeasurable tragedy.

The National Cancer Institute's efforts in childhood cancer include improving survival through better therapy and understanding fundamental biological mechanisms of carcinogenesis. For effective prevention of childhood cancer, much remains to be understood about its etiology. Of the known etiologic factors, both genetic (inborn) and environmental factors are at work, sometimes interacting, sometimes with one predominating.

Genetic Factors

As reviewed by a recent National Cancer Institute monograph, Genetics of Human Cancer, host determinants are especially apparent in childhood cancers. Children at high risk of cancer can be identified because of birth defects or their family history of neoplasia. At times, primary prevention of cancer is possible in childhood by removal of the nonvital organ at risk. For example, removal of the large bowel to prevent polyps from becoming malignant, removal of the thyroid gland to prevent thyroid cancer, or removal of gonads to prevent testicular cancer. Primary prevention can also be achieved through genetic counseling of persons with one of over 200 mendelian traits which predispose to malignancy.

Over the past fifteen years, the Institute's Epidemiology branch has advanced the clinical and preventive importance of the overlap between childhood cancer and birth defects. For example, children born with sporadic absence of the irises (aniridia) or with overgrowth of one side of the body (hemihypertrophy) are closely followed because of their high risk for Wilms' tumor of the kidney.

The presence of close relatives with cancer, especially sibs, can identify individuals who should be screened for malignancy. In recent years, Cancer Institute physicians have contributed to the early diagnosis of breast cancer, melanoma, Waldenstrom's macroglobulinemia and renal cell carcinoma during studies of "cancer families."

Environmental Factors

The discovery of asbestos as a carcinogen arose from detecting an excess of mesothelioma (a type of lung cancer) in adults who as children played near an asbestos mine. F. Li, of the Institute's Clinical Studies Section in Boston, has submitted a report of a mother and child who developed mesothelioma perhaps because of asbestos brought home by the father who himself had pulmonary adenocarcinoma and asbestosis. Such rare instances underscore the possible childhood origins of adult cancer. Candidate environmental agents under study are solar and gamma radiation; drugs such as diethylstilbestrol, androgens, and immunosuppressants; viral agents; nutritional status; smoking; and sex. In a few instances sufficient information justified preventive and surveillance efforts, e.g., the offspring at risk for genital tract cancer because their mothers took diethylstilbestrol during pregnancy; young adults at risk for thyroid neoplasia because of childhood radiation exposures; and children with xeroderma pigmentosum, now shielded from ultraviolet radiation to prevent skin cancer. Of special concern are studies of the late somatic and genetic effects among survivors of childhood cancer with the aim of minimizing the risk for second primary tumors arising from possibly carcinogenic anti-cancer therapy. The potential carcinogenicity of cytotoxic agents given for nonmalignant childhood disorders is also under study.

Carcinogenesis In Utero

The discovery of diethylstilbestrol as the first known transplacental carcinogen in humans launched a laboratory search for animal models and sharpened clinical attention on additional potential prenatal environmental carcinogens. In utero x-radiation has been suspected of uniformly increasing the risk of childhood cancer, but corroborating evidence is lacking. Several agents that cause birth defects are also carcinogens, but usually by differing mechanisms: alcohol, smoking, alkylating agents, radiation, androgens, and diethylstilbestrol.

Viruses

Viruses are suspected of being causally involved in lymphoid malignancies in children. Leukemias in several other species are known to be caused by viruses, and apparently related virus particles have been found in some human leukemia patients. Thus far, the firmest evidence for viral induction of a childhood malignancy concerns the Epstein-Barr virus (EBV) and Burkitt's lymphoma. Burkitt's lymphoma occurs primarily among certain African children, although there have been reports of non-African cases, including some in the United States. EB virus is also associated with nasopharyngeal carcinoma and is further believed to be the causative agent of infectious mononucleosis. If the same virus is indeed responsible for both the benign and malignant disease, it is important to determine the conditions which influence both its activity and the host response.

Early Diagnosis

Early diagnosis of those cancers which cannot yet be prevented offers the best opportunity for arresting the malignancies and allowing the patient to live a normal life. Patients who are at high risk of developing cancer should, therefore, be screened regularly so that any tumor which occurs can be diagnosed at the earliest possible time. Early diagnostic methods currently in use and those being developed are applicable to children and adolescents as well as to adults.

Treatment

The treatment program supports several individual studies, both intramurally and extramurally as well as the only national cooperative group devoted solely to research in childhood malignant diseases. These studies utilize a combined modality approach utilizing chemotherapy, immunotherapy, radiotherapy and surgery. These studies involve all childhood cancers, but especially childhood leukemias, non-Hodgkin's malignant lymphomas, soft tissue sarcomas, osteogenic sarcoma, neuroblastoma, aplastic anemia and histiocytosis as well as Wilm's tumor, Ewing sarcoma and Rhabdomyo-sarcoma. Other areas of clinical investigation that are stressed include hematologic support and bone marrow transplantation and diagnostic and preventive techniques applicable to the infectious complications of the compromised host.

Funding by Program Area

	FY-1977 (dollars in thousands)
Genetic Factors	$4,810
Environmental Factors	6,130
Carcinogenesis In Utero	1,510
Viruses	1,510
Early Diagnosis	1,810
Treatment	8,800
Total NCI	$24,570

G. "Describe the activities of the NCI relating to nutrition. Please provide a budgetary expenditure breakdown of NCI nutrition-related programs for FY 1976 and FY 1977 with appropriate subcategorization, i.e., research into cause, prevention, diagnosis, treatment, dietary maintenance of patients, and/or other appropriate categories."

In response to a Congressional mandate, the National Cancer Institute has developed a Diet, Nutrition and Cancer Program (DNCP), to develop and disseminate information on diet and nutrition in the causation of cancer and the treatment and rehabilitation of the cancer patient. In addition to DNCP activities, other nutrition-related research is done in the various components of the NCI.

The term nutrition research, as defined by the NIH Nutrition Coordinating Committee, includes studies designed to assess the metabolic and behavioral mechanisms and consequences of food or nutrient intake in the intact organism, including man, and investigations involving nutrient variables at the cellular or subcellular level. This definition also includes:

- Research designed to elucidate the metabolic role or function of nutrients in both animal models and man.
- All studies concerned with genetic-nutrient-environmental interactions where a nutrient is a variable.
- Dietary studies expected to produce significant changes in health status, including the maintenance of health and the treatment of disease in man. Such studies might include clinical trials, epidemiological studies, metabolic studies, surveillance, and nutritional status monitoring studies.

It is apparent that diet and nutrition are extremely important as support to cancer treatment (surgery, radiotherapy, chemotherapy) and rehabilitation, and that nutrition may be a feasible therapeutic approach in itself. The Diet, Nutrition and Cancer Program supports research projects to elucidate the role of diet and nutritional status in the causation of cancer and thus to define prudent dietary habits that may prevent cancer. This will also have preventive implications beyond cancer.

The DNCP also supports research to increase appetite and food utilization in the cancer patient, and to provide nutritional support during therapy and rehabilitation.

The DNCP also coordinates its research programs in diet and disease with those of other institutes and federal agencies, and formulates public education messages which recommend prudent dietary habits. The program has prepared, in collaboration with the American Cancer Society and the Candlelighters, two practical Dietary Handbooks for the nutritional management of the adult and pediatric cancer patients.

Cancer patients are known to become wasted and nutritionally depressed when bearing actively growing tumors. This often results in alterations in the hosts' immune system and tolerance to treatment. Clinical trials are now underway to determine the potential benefit for cancer patients of receiving high levels of nutrients, that is, hyperalimentation while undergoing therapy, and also to evaluate the impact on the patients' immune and metabolic functions. Several of these studies have been added to existing clinical trials which are utilizing a known therapy in order to make comparative evaluation of the effects of these known therapies with and without hyperalimentation. The results of these studies should be available in 2 to 3 years.

NCI: Nutrition Research Program for FY 1976 and FY 1977

Categories of research	FY 1976*	FY 1977*
Cause and Prevention	$2,043,505	$5,840,310
Nutrition Epidemiology	2,478,092	2,324,856
Dietary Maintenance	3,562,035	2,365,652
Nutritional Therapy	786,090	471,419
Information, Education, Support, etc.	524,705	4,760,366
TOTAL	$9,394,427	$15,762,603

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*The FY 1977 figures were developed based on the definition used by the NIH Nutrition Coordinating Committee (NCC). This definition is much broader than that used to develop the FY 1976 figures. Therefore, this table does not represent comparable data. Comparable figures (based on the NCC definition) for FY 1976 have not been developed.

H. Current status of Bioassay Program. Does NCI plan to expand it? Are there limitations requiring Congressional action?

The Institute has experienced numerous managerial problems with the Bioassay Program over the past several years. What began fifteen years ago as a minor adjunct to basic research programs was expanded rapidly on passage of the Cancer Act in 1971. Although additional funds were available, adequate additional staff was not provided for the expansion. As a result several contractors were engaged to perform chemical testing in animals. It quickly became clear that the contractors needed closer managerial surveillance. Consequently, with staff still at a premium, a prime contractor was hired to manage the work of other contractors. Within a short time it became evident that delegation to a prime contractor was also frought with problems. After a management consultant, at NCI's request, reviewed contractor performance and NCI management needs, the primary problems of the program came to the attention of Congressional Appropriations Committees. These problems related to ineffective completion, evaluation and publication of the results of chemical tests done by the contractors. Specifically, it was determined that some 200 chemical tests were underway at contractor facilities, but were not completed, evaluated or published. NCI made clear the need to allocate additional staff, and Congress assisted by designating an additional 60 positions in FY 1976 for use by the Bioassay Program. Meanwhile, an NCI reorganization in early 1977 brought additional managerial attention to the program, and a National Clearinghouse for Environmental Carcinogens was established to enlist external resources to help NCI improve the program. The program manager resigned for personal reasons in early 1977, necessitating recruitment of a replacement. Recruitment against the 60 new positions was initiated. The prime contract was renegotiated and strengthened to implement recommendations of the management consultant. Intense effort since mid-1977 has been directed at reducing the backlog of 207 chemicals on test.

The time required to complete each of the experiments comprising the backlog of chemical bioassays is difficult to predict. The experiments were not all conducted in the same way. Until the analysis of each experiment has begun, one cannot foresee what problems will be encountered in evaluating the adequacy of the experiment or the significance of the results. In many instances it is necessary, for example, to re-examine the tissues and to confirm or correct the diagnosis of the pathologists before statistical analysis can begin.

At the present rate of three or four reports per week, it is estimated that the backlog will have been completed and reported to the regulatory agencies by September 30, 1978. The reporting of the results of the bioassays is urgent; however, the analyses of the bioassays must be careful, thorough, and scientifically accurate.

During 1977, despite overwhelming activity directed towards reduction of the backlog, an additional 32 chemicals were entered into the test system.

NCI in FY 1978 anticipates complete elimination of the backlog and entry on test of an additional 90 chemicals. In FY 1979, it is expected that the program will be expanded so that 100 chemicals will be placed on test.

NCI continues to experience difficulty in recruiting adequate qualified staff to manage the program. Half of the 60 positions made available in FY 1977 remain unfilled. This is attributable to the national shortage of qualified toxicologists and veterinary pathologists, all of whom are in high demand.

While the Institute appreciates Congressional interest in, and concerns about this vital program, we believe that its problems lend themselves to administrative resolution, and no Congressional action is seen as needed at this time.

I. Question: Please describe and give current status of the drug trials supported by NCI.

Answer: Clinical drug trials sponsored by NCI follow a logical sequence of events covering the total span of studies from the administration of a new drug to the first patient to the development of data justifying the commercial marketing of a useful agent. These studies are divided into four phases.

Following the identification of a new drug worthy of clinical trial, the completion of all necessary preclinical studies, and the filing of an Investigational New Drug Application (IND) with the Food and Drug Administration, Phase I studies are initiated in advanced cancer patients. These studies establish the maximum tolerated dose at various schedules of administration, the pattern and quality of toxicities encountered, pharmacology and pharmacokinetics of the drug where possible, and observation of possible antitumor effects, although activity at this stage is not required for further pursuit of the drug. Once a tolerable dose and schedule have been established, Phase II studies are initiated to determine the activity of the drug in patients with evaluable and measurable disease in a spectrum of malignancies. Phase I and Phase II trials are supported primarily by NCI contract, although some grant-supported investigators participate.

Drugs demonstrating significant activity in one or more types of human malignancy are then evaluated more broadly in that malignancy in order to compare the activity relative to that of other drugs (Phase III) and then to explore the utility and safety of the drug in combined modality studies (Phase IV). These studies are carried out primarily by the grant-supported clinical cooperative groups.

At the present time there are 11 drugs in Phase I, 12 drugs in Phase II, and 26 drugs in Phase III and Phase IV. At the later stages of evaluation, drugs are frequently undergoing many different types of evaluation simultaneously, and one cannot, therefore, differentiate drugs wholly into Phase III or Phase IV.

It should be pointed out that most drugs, even after reaching the commercial market, still undergo further Phase III and Phase IV evaluation in the continuing effort to improve their utility alone or in combination with other drugs and modalities. At the present time, 20 commercial drugs are involved in such studies.

J. Please indicate the types of personnel that NCI has difficulty in recruiting for permanent positions if this is a problem.

NCI continues to experience extreme difficulty in recruiting veterinary medical officers, pathologists, toxicologists, and, to a lesser degree medical officers and mathematical statisticians.

N. Does NCI need more epidemiologists? Animal Pathologists? Environmental Toxicologists?

In order to continue the expansion of the environmental epidemiology effort, additional epidemiologists/statisticians are needed at the doctoral and masters levels. The enlarged staff would enable us to augment existing project areas and initiate new lines of research.

Some specialists are very difficult to recruit. For instance, within the Carcinogenesis Testing Program there are problems in recruiting scientists in scarce specialties, notably toxicology, veterinary pathology, laboratory animal medicine, and industrial hygiene. Needed immediately are five toxicologists, four veterinary pathologists, two laboratory animal verterinarians, and one industrial hygienist. The veterinary pathologists and laboratory animal veterinarians must be specialty-board certified to represent the Government in court.

Among the problems in recruiting are (a) the absence of civil service registers for the first three categories, (b) the competition from other Federal agencies, and (c) the comparatively low pay scale in Government.

✓. What new programs or changes in existing programs will be undertaken by NCI to respond to the generally accepted notion that most cancer is preventable?

In terms of strategy for fighting cancer, clearly the best approach is to achieve maximum prevention. Here indeed, there are promising new approaches opening before our eyes. At the same time however, there is a mounting sense of urgency, growing out of confusion and clamour about the potential dangers of manmade carcinogens. In this subject area, the scientific problems are complicated and confounded by regulatory considerations. Hence, there is need for increasingly close communication among scientists, regulators, lawmakers, and society at large.

Ultimately, prevention is the most effective approach to the control of cancer or any other disease. The role played by factors in the environment in the initiation of the cancer process has been of public, congressional, and scientific concern for many years. From the standpoint of scientific study, the problem is extremely complicated; there are an almost incalculable number and variety of environmental factors, both naturally occurring and introduced by man, acting alone or in limitless combinations and over different periods of time. Nevertheless, research has been conducted and progress has been made. However, the current estimates that a large percentage of all human cancers is due to environmental factors have served to greatly intensify the level of concern and the degree of interest in the activities of the Federal Government and especially the National Cancer Institute.

Other Federal agencies also are involved in carcinogenesis research in conjunction with carrying out their missions, e.g., the Food and Drug Administration, the Environmental Protection Agency, the National Institute for Occupational Safety and Health, and the Occupational Safety and Health Administration, in support of their regulatory mission, and the National Institute of Environmental Health Sciences as part of its broad environmental research responsibility. Thus, in addition to conducting and supporting research, NCI has paid increasing attention to the establishment of interagency coordinating groups to assure that cooperative efforts between NCI and other Federal agencies take place, where appropriate, to avoid unnecessary duplication of effort and to assure an effective flow and interchange of information on a timely basis.

Of the 80 to 85 percent of all cancers thought to be environmentally related, thus implying that they are preventable, 40 percent of those in males are directly related to cigarette consumption and thus preventable with current knowledge: 1) The Secretary of DHEW has launched an anti-smoking campaign with which we are working closely and heartily endorse. Cigarettes much lower in tar and nicotine have been produced and are gaining wide acceptance. 2) We have established a collaborative effort with the FDA Bureau of Radiological Health to monitor and reduce delivered doses of x-ray used mammography. 3) The bioassay program which screens for potential chemical carcinogens has been streamlined and reports are forthcoming at a more rapid rate. 4) Occupational exposure accounts for about 5 percent of cancer. In this area we have established the NCI Occupational Cancer Task Force--composed of representatives of the various NCI components which have occupational cancer activities--to review on-going activities and recommend additional acitivities for the future. They are meeting regularly with representatives of unions and industry. 5) Some believe that nutritional factors contribute to some common types of cancer, particularly breast and colon-rectum. The evidence for this is indirect at this time, so we are increasing our research in this area. 6) During the coming year the Cancer Control Program has plans to increase its prevention thrusts by placing more attention to lay and professional education, including workers in exposed industry.

M. What other changes in direction or emphasis will be recommended by the Director of NCI?

I do not envision any changes in emphasis or direction in the National Cancer Program (NCP) in the immediate future. Any large biomedical research effort whose initiatives range from cause and prevention to rehabilitation and whose approaches extend across the spectrum of research from fundamental to applied must of necessity be opportunistic. We must devote substantial efforts both to enrichment of the scientific base and to an enlighted exploitation of new leads that arise from such a pool of scientific knowledge. I can forsee a day when prevention will be the cornerstone of cancer-related activities; yet today we have only an incomplete understanding of the neoplastic process and of the causes of cancer. Accordingly, our techniques for prevention of cancers are often empirical, depending on the cancer in question. More substantial progress will probably depend on the development and exploitation of new knowledge rather than large scale investments in halfway technologies.

Thus even as we deliberately strive to create opportunities for preventing greater numbers of cancers, we may find that immediate benefits can also be achieved through substantial investments in detection and treatment.

As I see it, our greatest task will be to maintain a program balance that will best serve those afflicted with cancer while diminishing as rapidly as possible the respect that other members of our society will ever develop cancer.

III. National Heart, Lung, and Blood Institute

A. How many heart, lung, and blood centers is NHLBI currently supporting under Section 415 of the PHS Act? Does NHLBI require these centers to engage in so-called "technology transfer programs" such as continuing education programs for physicians and other health professionals, and if so, please describe these programs. Does NHLBI require these centers to conduct public information programs respecting heart, lung, blood vessel, and blood diseases? What are NHLBI's plans for FY 1978 and FY 1979 regarding the support of new centers under Section 415? Are any of these centers engaged in activities specifically involving heart, lung, and blood diseases afflicting children?

Answer: The National Heart, Lung, and Blood Institute's National Research and Demonstration Centers (NRDCs) play an important role in achieving many of the goals of the National Program by bridging the gulf between fundamental research and the application of research results in health care and disease prevention. The presence in a single center of scientists, physicians, and other professional personnel representing many disciplines creates an environment in which participants can interact and train young scientists in an efficient and productive way.

In FY'74, after a nationwide competition, the National Heart, Lung, and Blood Institute awarded NRDC grants to three institutions:

- The Center at the University of Vermont, College of Medicine, melds and intensifies efforts and resources for the control of respiratory disease.
- The Baylor College of Medicine in Houston has a Research and Demonstration Center which focuses on heart and blood vessel diseases, particularly atherosclerosis.
- The National Research and Demonstration Center at the Puget Sound Blood Center in Seattle is concerned with the improvement of procedures for the acquisition, processing, storage, distribution, and clinical use of blood and blood products.

The programs of the three established centers encompass a spectrum of health-related activities and approaches. These are serving as a blueprint for the design of a second generation of centers. The authorizing legislation under Section 415 of the Public Health Service Act indicates that the Centers "in addition to be utilized for research, training, and demonstrations be utilized for ... prevention programs for cardiovascular, pulmonary and blood diseases ..." including "programs to develop methods of intervention against those factors which cause individuals to have a high risk of developing such diseases" and "programs to develop health professions and allied health personnel highly skilled in the prevention of such diseases". The NHLBI does require the Centers to engage in so-called technology transfer programs.

Examples of some of these "transfer" programs are as follows:

- Application of preventive treatment and rehabilitative procedures to community clinics and hospitals as practiced in the academic research environment of the Baylor Cardiovascular Center.
- Employment of special ambulances equipped with telemetering equipment, permitting physicians in participating hospitals to monitor the clinical status of heart attack victims or other cardiovascular emergencies and to supervise their treatment while the patient is enroute to the hospital.
- Development of a state-wide network for surveillance, diagnosis, treatment, and control of tuberculosis, industry-related lung diseases, and other pulmonary disorders in ambulatory patients.
- A program for providing regional assistance in the management of respiratory diseases, employing an interhospital computer network for information storage and retrieval, data interpretation and analysis, aids in diagnosis and treatment, and the dissemination of new knowledge.
- Development of a computerized progressive care program, oriented to clinical problems of respiratory diseases, that will draw on and integrate the developing methodology and technology, provide technical assistance and quality control in clinical care, and evaluate the results of new programs within community hospitals.
- Dissemination of new knowledge via a television network linking seven medical care facilities and two university medical centers.
- Development of a patient education program employing self-instruction and audio-visual techniques to help patients understand the nature of their disease and so encourage their full cooperation in treatment and control measures.
- Assisting hospitals and clinics to make optimal use of available blood resources, encouraging use of the specific blood component required by the clinical situations, such as packed red cells, platelets or plasma fractions, rather than the "scatter-gun" approach of transfusing whole blood.
- Provision of training and education programs for laboratory technicians, medical students, hematology trainees, and physicians within the community.

The Institute further requires that as the public and professional education projects progress, and as the Center becomes more visible in its geographic area, the Center should develop an information capability. Thus, it would develop resources to respond to public inquiry and requests for printed materials. For example:

- o Development of a regional public information system on respiratory diseases in collaboration with the Vermont Lung Association and the State Health Department.

An additional requirement is that the education-information component of a center must include education-evaluation projects with specific objectives. Education is defined here as a process by which change is produced in knowledge, attitudes, and/or behavior of the public and/or health professionals related to the maintenance of health. The NHLBI views these education projects as efforts to reach the general public, health care providers, and the high-risk population (including patients) with information designed to promote and improve health practices. It is hoped that projects will also make contributions to the state-of-the-art of educational research in the health area. For example.

- o Implementation of community programs addressing alteration of risk factors strongly associated with increased susceptibility to coronary heart disease and its complications, such as acute heart attacks; in particular, the elimination or reduction of cigarette smoking and the modification of habitual dietary patterns (diets high in calories, total fats, and cholesterol) that tend to raise blood lipid levels.

The Institute however, views a Research and Demonstration Center as a national resource attached to a major medical complex and dedicated to working in close collaboration with the NHLBI to further the goals of the National Heart, Blood Vessel, Lung, and Blood Program through a multidisciplinary coordinated approach, providing a suitable training milieu and spanning the spectrum from basic through clinical research to demonstration and education for the applicability of the results of research. The demonstration and education components of the center, which must be equal in quality to the standards of excellence required for biomedical research, advance the state-of-the-art and provide for stringent evaluative procedures.

Plans for New Centers

During the past two years, the National Heart, Lung, and Blood Advisory Council and the National Heart, Lung, and Blood Institute have undertaken a comprehensive review of the centers concept and costs. The Council has reconfirmed its agreement with Congressional intent to further research validation and demonstration capabilities through national centers, and has developed an improved centers model to better both the quality and speed of information dissemination to the public and the health care professional. In addition to this revised center concept, the Council in its Annual Report for both 1976 and 1977 recommended an expansion of the Research and Demonstration Centers program. The legislative mandates calls for 30 centers; only three are now funded. Consequently, the Council recommended that 20 additional centers and $50 million be added to the ongoing program in fiscal year 1979. The Council noted that expanded support is vital to rapid and effective development of the prevention, control, and education effort. In view of competing resource requirements and constraints, however, the Council has concurred with the Institute's decision to defer solicitation of additional centers at this time.

Activities Specifically Related to Children

The Center concept is to help implement, expand and coordinate national activities aimed at closing any existing translation gaps and is to bring any new findings to the patient and primary care physician. While the three centers currently funded are broad in concept, but not focused on diseases which affect children, there are programs in these centers which are directly related to diseases which may have their origin in the first two decades of life.

At the Institute's Research and Demonstration Center at Houston, the Social Psychological Deterents in Schools project is reducing the onset of smoking in adolescents by modifying attitudes and behavior. Preliminary data, after two years, show a 50% reduction in smoking and behavior in 7th graders as a result of primary prevention techniques. A longitudinal study involving 10,000 adolescents is underway.

Another study of this Center is to analyze the transfer of nutrition knowledge into dietary behavior. The aims include the assessment of knowledge of students and their parents' development of teacher dependent and non-teacher dependent methods methodology.

At the Puget Sound Blood Center, a project is directed toward a hemophilia care program. This demonstration project is providing evidence that a blood bank is the ideal environment for hemophilia patient management and care. Such a project is aimed at the pediatric patient. Another study at this center involves research directed at identifying genetically-linked diseases in newborns.

8. Please describe and provide budgetary breakdowns for prevention and control programs supported by NHLBI under Section 414 of the PHS Act. For FY 1976 and FY 1977, how many organizations and/or individuals have requested NHLBI funding of programs under its Section 414 authority; how many applications were submitted for funding of these programs; how many of these applications were approved and funded; how many of these applications were approved but not funded?

Answer: While the National Heart, Lung, and Blood Institute has had authorization under Section 414 for prevention and control programs, there have never been specific appropriations allocated to implement these programs.

The Institute, impressed by the opportunities, needs, and importance of these transfer activities, has, however, responded to this mandate by implementing a number of prevention and control activities in the past five years by rebudgeting from other efforts.

Two examples of programs initiated by NHLBI in response to this prevention and control initiative are the National High Blood Pressure Education Program and the National Sickle Cell Disease Program.

National High Blood Pressure Education Program (NHBPEP). The mission of the National High Blood Pressure Education Program is to reduce death and illness associated with hypertension through an education program directed at both the general public and health professionals.

The National High Blood Pressure Education Program is coordinated by the National Institutes of Health (NIH), with the National Heart, Lung, and Blood Institute as the focal point. The collaborative government/private sector effort also involves the Food and Drug Administration (FDA), the Health Resources Administration (HRS), the Veterans Administration (VA), and the Department of Defense (DOD), as well as over 150 private sector organizations, including professional societies and associations, voluntary health organizations, certifying and accrediting bodies, pharmaceutical companies, labor management groups, and insurance companies. All are working together to focus attention on high blood pressure as a serious disease, but one which can be readily detected and controlled. Activities of the program include:

- A High Blood Pressure Information Center which answers public inquiries about high blood pressure and prepares and distributes free educational materials.

- A Community Consultation Service which has recruited and provided orientation for 30 non-Federal consultants to offer technical assistance to community programs and local personnel. The service has maintained a caseload of 60 active community programs and provided assistance to 210 communities.

- National High Blood Pressure Month in May sponsored or endorsed by 129 organizations and over 300 community groups. Approximately 55,000 kits containing education and detection guidelines were requested.

- National High Blood Pressure Coordinating Committee whose membership includes Federal, professional, and public agencies was organized to develop mutual policies and to define and promote areas for joint participation.

- Interagency Technical Committee Working Group on Hypertension is organized to stimulate and coordinate education and control efforts among Federal employee health service programs.

National Sickle Cell Disease Education Program

The National Sickle Cell Disease Program was initiated as a major collaborative effort to accelerate research in, and to improve diagnosis, control, and treatment of, sickle cell anemia. The National Institutes of Health (NIH) was named as the lead agency for the overall program and it is also responsible for its research and development activities. A National Sickle Cell Disease Advisory Committee, appointed by the Secretary of DHEW, developed recommendations on program direction and policy which resulted in the establishment of Comprehensive Sickle Cell Centers, Sickle Cell Screening and Education Clinics, a mission-oriented research and development program biomedical research, a public and professional education program, and a hemoglobinopathy training program.

The NHLBI, within the NIH, serves as the lead Institute and coordinates the activities of the overall program. The Health Services Administration (HSA) is responsible for some of the demonstration activities in education, testing, and counseling. Other agencies actively engaged in related sickle cell activities include the Center for Disease Control (CDC), the Department of Defense (DOD), and the Veterans Administration (VA).

- Activities of the Program include the development of a number of Screening and Education Clinics to identify the best techniques for testing, counseling, and patient referral. The Clinics have screened approximately 420,000 individuals during FY 1975. Of these, an estimated 40,000 will receive special counseling.

- A National Symposium on Sickle Cell Disease.
- A training program in the detection of abnormal hemoglobins and a series of hemoglobinopathy workshops have been conducted by the Center for Disease Control (CDC). A hemoglobinopathy laboratory manual has been published by CDC, and Reference Laboratories giving advice on the identification of abnormal hemoglobins have been established.

In addition to these model programs, the Institute has supported other activities under the prevention and control mandate; a budgetary accounting of programs for Fiscal Years 1976 and 1977 is provided in Table I.

Since the Institute has never specifically had 414 dollars, it is difficult to define in totality all applications submitted, approved, funded, and unfunded under this rubric. In fiscal year 1976 and 1977, however, the Institute did solicit through the grant (Request for Application (RFA)) or contract route (Request for Proposal (RFP)) several initiatives that fall directly into our prevention, education, and control mandate. Table II provides a statistical analysis of the applications submitted, approved, and funded under these solicitations.

TABLE I

NHLBI Prevention and Control Programs
(Section 414 of PHS Act)
(dollars in thousands)

	FY 1976	FY 1977
Division of Heart and Vascular Diseases		
Hypertension Education Research Grants	$ 740	$ 675
Hypertension Detection and Follow-Up	12,020	7,415
Hypertension Information Contracts	1,410	1,590
Hypertension Drug Costs	100	-
National Heart Research & Demonstration Center Component	1,030	1,035
High Blood Pressure State-wide Control Program	-	2,540
Nutrition Education	-	1,500
High Blood Pressure Control in the Work Setting	-	200
Pilot Evaluation Studies of Community HBP Control	-	540
Subtotal	$15,300	$15,495
Division of Lung Diseases		
Education Programs for Neonatal Respiratory Distress	$ 875	$ 780
Education Program for Treatment of Acute Respiratory Insufficiency	435	-
Self-Evaluation for Children with Asthma	-	450
Continuing Education in Pulmonary Medicine	500	475
National Lung Research & Demonstration Center Component	675	1,335
Task Force on Prevention, Control and Education	65	-
Subtotal	$ 2,550	$ 3,040
Division of Blood Diseases and Resources		
Sickle Cell Clinics	$ 3,500	$ 3,500
Sickle Cell Centers Component	4,535	4,010
Sickle Cell Education Contracts	310	-
National Blood Research & Demonstration Component	80	100
Subtotal	$ 8,425	$ 7,610
Total	$26,275	$26,145

TABLE 11

NHLBI Prevention and Control Programs
(Section 414 of PHS Act)

Program	Year	Applications*	Approvals**	Funded***
Div. of Heart & Vascular Diseases				
Hypertension Statewide Control Program	1977	22	13	4
Nutritional Counciling for Hyperlipidemia for Dietitians and Nutritionists	1976	18	9	1
Hypertension Control in the Work Setting (in review)	1977	30	18	3
Pilot Evaluation Studies of Community Hypertension Control	1977	23	5	2
Division of Lung Diseases				
Self Evaluation for Children & Asthma	1977	38	12	3
Continuing Education in Pulmonary Medicine	1976	22	5	4
Div. of Blood Diseases & Resources				
Comprehensive Sickle Cell Centers	1976	14	9	6
TOTAL		167	71	20

* The number of research applications from individual and/or organizations requesting funding.

** The number of research applications approved for funding

*** The number of research applications funded.

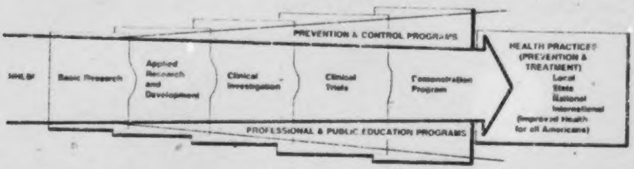
C. Please list each grant and contract that has been awarded relating to the prevention of heart, lung, blood vessel, and blood diseases during FY 1976 and FY 1977. Please provide the title of each grant or contract, the name of the principal investigator, the name and location of the institution conducting the project and the amount of each award.

Answer: It is, indeed, difficult to answer this question since a uniform definition of prevention has not been obtained. NIH has recently constituted an NIH Prevention Working Group and has addressed the perceived need for a clearer, more acceptable definition and description of NIH programs and activities in the area of prevention.

The ultimate goal, however, of all National Heart, Lung, and Blood Institute activities is prevention. Prevention-related program activities have existed in the Institute's mandate since the original act creating the Institute in 1948 and have considerably expanded and extended as an Institute responsibility by the Heart, Lung, and Blood Act of 1972 and its revisions.

The concept of prevention, however, can be interpreted by various individuals in quite different ways. Prevention can be defined as an intervention prior to the biological onset of a disease; or at a stage when a disease can be detected but is not symptomatic, or at a point when the goal is to delay, arrest or reverse the course of a disease or the definition may include some or all of these acts of intervention.

Prevention must at the same time be considered as a process that extends through the entire biomedical research spectrum from the acquisition of new knowledge through its application and validation, to its ultimate translation to practical health care principles and practice.


PREVENTION & CONTROL PROGRAMS
NHLBI
Basic Research
Applied Research and Development
Clinical Investigation
Clinical Trials
Demonstration Program
HEALTH PRACTICES (PREVENTION & TREATMENT)
Local
State
National
International
(Improved Health for all Americans)
PROFESSIONAL & PUBLIC EDUCATION PROGRAMS

Prevention does not begin and end with health care delivery, patient and physician education, or environmental change. Activities in the first three elements of the continuum; basic research, applied research and development, and clinical investigation are designated as "science base" activities; their role in the prevention spectrum is the development of information. The next element; clinical trials, recently designated as "application" is the stage where prevention information is validated. The final elements are demonstration and health practice implementation. It is here where prevention information is "transferred" or applied to the community at large. In the arena of the major heart, lung, and blood diseases, we do not know, with any certainty, what services to deliver or how; what facts to teach; or what environmental factors to change. Prevention encompasses basic research on etiology and pathophysiology so as to allow us to better understand basic biological processes like arteriosclerosis, hypertension, rheumatic and congenital heart disease, cardiomyopathies and infections of the heart and lung, injury, repair, and maturation. It also includes epidemiology, clinical investigation, and clinical trials that allow the development of associations, hypotheses and interventions, as well as their testing and validation. Finally, it must include expeditious translation and dissemination of proven facts to the health care professional and public through education and control activities.

An example of one prevention strategy that has moved from the "science base" and gone through the validation step (at least in regard to smoking and blood pressure control) to be transferred to the health care community, is the current attention to Cardiovascular Risk Factors. They were uncovered through clinical research. They have been validated by prospective epidemiological studies and clinical trials. Increased public awareness of, and attention to their reduction is now a major prevention goal.

The "transfer" stage of the prevention concept is most often used when referring to NIH activities. Consequently, the listing of grants and contracts below encompasses this end of the spectrum. NHLBI, however, spends greater than $50 million dollars in the validation of prevention information in its clinical trial program and considerable more in "science base" programs to gain and develop prevention information.

D. Please describe, and provide budgetary breakdowns for, the activities of the NHLBI during FY 1976 and FY 1977 relating to exercise as a factor associated with heart, lung, blood vessel, and/or blood diseases.

Answer: Regular exercise and physical activity are generally regarded as beneficial to health, and they are thought to reduce the risk of heart disease. On the other hand, intense and unaccustomed or irregular exercise may precipitate acute heart disease in those who have pre-existing heart disease, whether known or unrecognized.

NHLBI activities related to exercise as a factor associated with heart, lung, blood vessel, and/or blood diseases include research designed to understand mechanisms of exercise physiology, in large part to provide an underpinning for clinical studies on exercise and its role in health. Some of the NHLBI projects are focused primarily upon exercise (I). Other projects (II) include exercise as one of several factors under study, but it is important to recognize that in some of these projects exercise is only a small facet of a very broad program. These activities are tabulated below:

	FY 1976	FY 1977
(I) Primarily exercise and		
disease (in man)	$ 61,855 (2)	$ 250,466 (5)
experimental disease (in animals)	286,840 (3)	368,687 (3)
exercise physiology	880,252 (9)	890,741 (8)
Subtotal	1,228,955 (14)	1,509,894 (16)
(II) Exercise identified as part of broader program	17,841,956 (76)	17,148,410 (73)
Total	$19,070,911 (90)	$18,658,304 (89)

(numbers in parentheses are numbers of grants - contracts)

Almost all of the research dealing with exercise and disease relates to heart disease. Studies on exercise physiology include a significant fraction of pulmonary as well as cardiovascular physiology and a small amount of research involving blood.

In yet another group of studies, particularly clinical trials such as the Coronary Artery Surgery Study, Multiple Risk Factor Intervention Trials, etc., the exercise and activity status of participants is carefully recorded and analyzed, but these latter studies have not been included in the tabulation above.

E. Please describe the activities of the NHLBI related to nutrition and provided a budgetary expenditure for FY 1976 and FY 1977 using appropriate subcategories.

Answer: The NHLBI has developed a program to study the effects of diet on cardiovascular disease. This program has six operational objectives: to define the effect of diet on blood lipids; to define the effect of diet on coronary heart disease morbidity and mortality; to develop comprehensive tables of food composition; to improve methods for collecting, recording and evaluating dietary data; to disseminate scientific advances to the professional and lay communities; and to achieve dietary change.

Definition of the effect of diet on blood lipids and lipoproteins: This is being pursued through three avenues of research: epidemiologic studies, clinical trials and basic research.

An epidemiologic study, the Lipid Research Clinics (LRC) Prevalence Study is an internationally-based study of the prevalence of dyslipidemias (lipid diseases) in defined populations. Ten clinics in the United States, one in Canada, two in the Soviet Union and one in Jerusalem are participating. This is the first time such a large-scale multi-centered collaborative population study, using absolutely comparable methodology, has been undertaken. It is hoped that, with large numbers and more refined methodology, dietary influences on lipid transport diseases, where they exist, will be detected.

In addition, the Institute continues its support of research aimed a studying basic mechanisms through which dietary components contribute to vascular disease.

Specialized Centers of Research (SCOR's) are established to focus resources facilities and manpower on specified problems to expedite the development and application of new knowledge. The Arteriosclerosis SCOR Program is concerned with particular components of human and animal diets in relation to hyperlipidemia and to the etiology of arteriosclerosis and coronary heart disease. Although a major emphasis of these studies is to establish and characterize the basic mechanisms by which specific dietary components (fats, lipids, and carbohydrates) contribute to vascular disease, several of the Centers are involved in whole or in part, in studies to determine the extent to which dietary manipulation can prevent or modify the course of risk factor development and disease in humans.

Nutritional components of regular research grants consist primarily of basic research into the role of specific nutrients in metabolic processes related to heart disease. These are being explored in a variety of ways using both animal models and human participants.

Definition of the effect of diet on CHD morbidity and mortality: Clinical trials have been designed to investigate the effect of dietary change on coronary artery disease. Here the focus is primarily on the removal from the diet of saturated fats and cholesterol, and the effects of this intervention on plasma cholesterol per se, and hopefully on the long-term effects on coronary disease. The Institute currently supports several such trials. During the next decade it is hoped that these studies will provide definitive evidence to support the positive findings from animal studies and suggestive epidemiologic data that lowering of blood cholesterol is beneficial.

Development of comprehensive tables of food composition: The ability to make meaningful interpretations of dietary data will depend on the accuracy of the available nutrient data.

Consequently, the Institute has entered into a collaborative program with the U.S. Department of Agriculture (USDA) to underwrite the acquisition of certain nutrient data that will not only serve the needs of the NHLBI but benefit the entire nutrition community. The Institute supports literature searches as well as basic food analyses for fatty acid and cholesterol. This activity has accelerated the updating of USDA Handbook No. 8 "Composition of Foods."

As a consequence of these activities the Institute in collaboration with USDA and food manufacturers has developed what is probably the most up-to-date and comprehensive food table currently in use for calculating nutrient intakes.

NHLBI has also recently supplied funds to the Nutrient Composition Laboratory (USDA) to pursue development of automated analytical techniques and for direct analyses of foods.

Improved methods for collecting, recording and evaluating dietary data: The current clinical trials and epidemiologic studies have provided an opportunity to develop, test, and refine procedures for measuring nutrient intake in populations. It is hoped that this activity will result in a standardized measurement such as has been achieved for other physiologic parameters in epidemiologic research. Much of this activity is housed in a central facility established by the Institute to code dietary recalls, maintain the food table and assist with training and continuing education of the dietician.

Dissemination of information: The Institute recognized the importance of rapid transfer of knowledge from the research area to the community. A research and demonstration center for atherosclerosis has been funded which has an extensive community-based nutrition component. We have also developed handbooks for the dietary management of hyperlipoproteinemia to provide information to physicians and their patients at high risk (who have very high cholesterol or other blood lipids).

Achieving dietary change: Achieving dietary change is not only the primary objective of clinical studies, but ultimately at such time as there is a clear understanding of the role of diet and heart disease, the goal will be to achieve change on a massive scale. In FY 1976, the Institute sponsored a national workshop on Nutrient and Behavioral Modification: another is planned for this year. These workshops, as well as other Institute-sponsored conferences, have allowed us to bring biomedical and behavioral scientists together to confront the problems of altering dietary patterns. Currently, techniques and materials in education and behavior modification are being developed, tested and evaluated with the clinical trials and community-based programs. One project specifically seeks to determine what factors are necessary to achieve and maintain dietary compliance. Another is evaluating the use of the mass communications media to change health behaviors. It is hoped that these programs and those planned for the future will point the way to effective community action.

Specific budgetary and subprogram details are provided:

1. A summary table listing program names and budget.

2. Program descriptions which are identical or shortened versions of material submitted to the NIH Nutrition Coordinating Committee in the recent past.

SUMMARY
NHLBI NUTRITION PROGRAM FOR FY 1976 AND FY 1977

PROGRAM TITLES (includes Grants and Contracts)	NUTRITION DOLLARS FY 1976 *	TQ '76 *	FY 1977 *
The Role of Nutrition in Arteriosclerosis and its sequelae	4,811,148	1,238,528	5,334,190
Arteriosclerosis (SCOR's)	2,968,830.*		4,548,548
Determinants of High Blood Pressure in Children	416,356		593,608
Infantile Respiratory Distress Syndrome (IRDS)	45,354		61,449
Community-based Media-intensive Education Field Trial for Cardiovascular Health	183,478		565,306
Research and Development Center for Heart and Vessel Disease	325,135		336,471
Lipid Research Clinics: Prevalence Study and Coronary Primary Prevention Trial	3,523,875		3,513,445
Multiple Risk Factor Intervention Trial (MRFIT)	6,936,804		4,158.154
Hypertension Detection and Follow-up Program (HDFP)	254,502		252.375
Development of Comprehensive Tables of Food Composition	125,000		345,704
Pilot Studies on Alteration of Diet by Behavioral Means	Staff Pilot Project: No Extramural Dollars		
Intramural Research	550,000		687.000
Extramural Training Program	27,728	197,960	237 604
TOTALS	20,168,818	1,436.488	20,734.354

* [illegible]

NHLBI EXTRAMURAL NUTRITION PROGRAMS FOR FY 1976 AND FY 1977: PROGRAM DESCRIPTIONS

Title: The Role of Nutrition in Arteriosclerosis and its sequelae

This broadly-based program is composed of investigator-initiated grants covering an array of areas all focused on the role of nutrition in arteriosclerosis and its sequelae. Among the topics can be found research on: the effect of diet on blood lipids and lipoproteins; the effect of diet on coronary heart disease morbidity and mortality; dietary implications of the exacerbating effects of diabetes on arteriosclerosis and its sequelae: and effects of vitamin and mineral nutrition on thrombos formation.

Title: The arteriosclerosis Specialized Centers of Research

This program is concerned with particular components of human and animal diet in relationship to hyperlipidemia and to the etiology of arteriosclerosis and coronary heart disease. Although a major emphasis of these studies is to establish and characterize the basic mechanisms by which specific dietary components (fats, lipids, and carbohydrates) contribute to vascular disease, several of the Centers are involved, wholly or in part, in studies to determine the extent to which dietary manipulations can prevent or modify the course of risk factor development disease in humans.

Title: Determinants of high blood pressure in children

This investigator-initiated grant program covers a number of factors; including dietary components and overweight, which are involved with the etiology of high blood pressure in children and consequently with the prevention of high blood pressure in children. There will be greater emphasis on dietary aspects of high blood pressure research, especially in infants, children, and the obese in succeeding years.

Title: Infantile respiratory distress syndrome (IRDS)

IRDS is the single most frequent cause of death during the neonatal period. Mortality is highest among premature infants; most of these infants die with signs of respiratory distress. A small but important fraction of the risk concerns maternal nutrition, (consumption of lecithins and other prospholipids) which along with steroid therapy, is being studied as a means of reducing the risk of premature birth and consequent risk of IRDS.

Title: Community-based Media Intensive Education Field Trial for Cardiovascular Health

In this grant program, diet is an important component of a continuing three community experiment designed to determine whether health education can reduce the risk of cardiovascular disease. Two communities were subjected to extensive mass media campaigns, and in one of these, individual counseling also was provided to a subset of high-risk people. The third community served as control. Residents of each community were interviewed and examined before the campaigns began and at annual intervals, thereafter, to assess knowledge and behavior related to cardiovascular disease (e.g., diet and smoking) and to chart physiological risk factors (e.g., plasma cholesterol, relative weight, blood-pressure).

Thus far, analyses over a two year experimental period are available. Risk of cardiovascular disease increased in the control community, whereas in the treatment communities there was a substantial and sustained decrease in risk. In the experimental community which had, in addition, face-to face counseling, the initial improvement was greater but at the end of the second year the decrease in risk was similar in both treatment communities.

Title: Research and Demonstration Center for Heart and Vessel Disease

A number of nutrition education projects can be found among the education and demonstration activities at the Center. Examples of their projects include: (1) a cooperative effort with local restaurants in which nutritious. low cholesterol meals are designed and placed on the menues and advertisements to the public about the heart-healthy nature of the meals. (2) Another project enrolled 1,000 people from the community and tested the ability of 3 plans to lower blood cholesterol: a) the Mayo Clinic diet; b) the Mayo diet, plus nutritional counseling; and c) the Mayo diet, counseling and behavior modification. Plan c) was most effective, followed by plan b), followed by plan a).

Title: The Lipid Research Clinics: a) Prevalence Study and b) Coronary Primary Prevention Trial

a) This is an internationally-based contract-supported study of the prevalence of dyslipidemias (lipid diseases) and their association with diet and cardiovascular disease in defined populations. Included in the study are 10 clinics in the U.S., one in Canada, two in the Soviet Union and one in Israel. This is the first time that such a large-scale multi-center collaborative population study, using comparable methodology, has been undertaken. The large numbers and more defined methodology aim to enhance detection of dietary influences on lipid transport diseases where they exist. There are preliminary indications that diet in the United States is shifting to lower cholesterol and saturated fat intake. Since cardiovascular mortality is dropping in the U.S., this dietary change may be a contributing factor.

b) This trial involves more than 3,600 men between 35 to 59 years of age and tests whether lowering cholesterol in hypercholesterolemic but otherwise healthy subjects will reduce or slow the development of premature coronary heart disease. The nutritional objectives are to achieve moderate, long-term dietary intervention in patients taking cholesterol lowering drugs and control groups to assess the prestudy diet and to evaluate group changes in dietary intake after counseling.

Title: Multiple Risk Factor Intervention Trial (MRFIT)

This clinical trial tests whether intervention in a group of 12,000 men 35 to 54 years old, who are at above average risk of death from coronary disease can yield a 50% reduction in mortality from coronary heart disease. The intervention component of this trial is designed to bring about changes in eating habits to achieve a reduction in weight and serum cholesterol; there is also a relationship to hypertension through association between weight cont and sodium and potassium intake. The dietary intervention program utilizes techniques and knowledge of group dynamics and behavior modification. Particularly important to this study is simultaneous evaluation of several risk factors. The nutrition methodology used here is standardized with that used in our lipid research studies to facilitate comparison among different studies

Title: The Hypertension Detection and Follow-up Program (HDFP)

The objectives of the program are to determine the effectiveness of antihypertensive therapy in reducing morbidity and mortality in a wide spectrum of persons with elevated blood pressure in 14 communities and to provide a direct measure of the prevalence, severity and current treatment status of representative white and black populations with high blood pressure in these 14 communities. A further objective is to determine the extent of attainable reduction of complications of high blood pressure by an organized screening and blood pressure management program. A small but important aspect of efforts to attain reduction of high pressure and the complications thereof consists of dietary measures to reduce overweight and to control salt intake.

Title: Development of Comprehensive Tables of Food Composition

The ability to make meaningful interpretations of dietary data depends upon the accuracy of the available nutrient data. The Institute has entered into a collaborative program with the U.S. Department of Agriculture to underwrite the acquisition of certain nutrient data that will not only serve the needs of the Institute, but also benefit the entire nutrition community. The Institute also supplied funds to the Nutrient Composition Laboratory of USDA to pursue development of automated analytic techniques for direct analyses of food and improved methods for collecting, recording, and evaluating dietary data. Current clinical trial and epidemiological studies have provide the opportunity to develop, test, and refine methods for measuring nutrient intake in populations. The aim of this activity is to yield standardized measurement methods such as has been achieved for other physiological parameters in epidemiological research. Much of this activity is housed in a central facility established by the Institute to code dietary recalls, maintain the food table, and assist with the training and continuing education of dieticians.

Title: Pilot Studies on Alteration of Diet by Behavioral Means

These studies take two forms: a) behavioral research designed to reveal factors that influence food selection in cafeterias, so that the populace will select low calorie, heart-healthy diets which have good nutritive values; and b) arrangements with supermarket chains and fast food chains to make available foods for heart-healthy diets. In both instances newly-devised media approaches are being used to attract and hold attention of purchasing public. Monitoring food purchased in cafeterias and in supermarkets is done through identification of food type on cash register tapes. Proof of the effectiveness of these behavior alteration approaches to nutrition education will await comparison of the food eating habits several months to a year after the project has been completed.

INTRAMURAL RESEARCH

1. The relation to the hypertension of patients with sodium sensitive hypertension to cardiac output and to the adrenergic nervous system.

"Salt-sensitive" hypertensive patients cannot excrete sodium "loads" as readily as those with "non-salt sensitive" hypertension. The increment of retained sodium, with a corresponding increase in blood volume, leads to an increase in cardiac output as measured by echocardiography and is associated with a greater rise of blood pressure in salt sensitive patients. The mechanism by which dietary sodium influences blood pressure in the two groups in not related to changes in plasma renin activity or aldosterone with salt loads, but may be due to that of the response of the autonomic nervous system to these loads: in non-salt sensitive patients autonomic "drive" may be more easily lowered by salt-loads, as compared with salt-sensitive patients in whom the persistence of such drive contributes to the rise of blood pressure.

The study of the nephrogenous cyclic AMP in patients with hypercalciuria and in normal volunteers.

In hypercalciuric patients and normal volunteers, dietary protein and acid-base content is varied and changes measured in calcium and phosphorus metabolism. In addition, nephrogenous cyclic AMP is measured since it reflects rapid changes in parathyroid activity and can serve as an index of the entire spectrum of parathyroid.

2. NHLBI Type II Coronary Intervention Study.

The primary aim of this study is to determine whether lowering the LDL in patients with premature coronary artery disease and Type II will slow, stop, or reverse the progression of coronary artery disease. This is a test of the lipid hypothesis in a specific group of high risk patients.

3. Hyperlipoproteinemia and atherosclerosis: changes in plasma lipoproteins and apolipoproteins induced by cholesterol feeding.

The purpose of this study is to correlate the changes in plasma lipoproteins in animals fed cholesterol-rich diets with the development of accelerated atherosclerosis in varios animal studies. The hyperlipoproteinemia has certain consistent features which include the occurrence of beta - very low density lipoproteins, an increase in low density lipoproteins, and the appearance of a unique lipoprotein, the HDL. The occurrence in increased concentration of a specific apoprotein (arginine-rich apoproteins) with all these cholesterol induced lipoproteins suggests an important role for this protein in cholesterol metabolism and possibly in accelerated heart disease.

Animal models for study of atherosclerosis.

The purpose of this study is to establish the proper dietary and metabolic conditions necessary to induce experimental atherosclerosis in various species which have characteristics similar to man. In three species, dog, miniature swine, and Patas monkey, this has been accomplished. The source of dietary fat has been found to have a profound effect on the type, distribution and severity of the atherosclerosis. Atherosclerosis produced by diets containing beef tallow, in addition to being severe, is associated with gross arterial thrombosis and occlusive vascular disease.

The role in hyperlipoproteinemia of a high-density lipoprotein induced by cholesterol feeding.

Outpatient normal volunteers ate 6 eggs daily and diets high in saturated fat. The plasma cholesterol concentration increased in 5 subjects during the first two weeks but had returned to pre-study levels when the study was terminated at the end of 4 weeks. In the high density lipoproteins of all subjects, a subfraction changed in that it developed an increased content of the arginine-rich apoprotein (ARP). When the ARP content increased, the HDL were able to bind to cells in tissue culture and inhibit cellular cholesterol synthesis. HDL without ARP were not able to bind to high affinity binding sites.

TRAINING IN NUTRITION

Description of program:

The NHLBI mandate includes research on diseases of the heart and blood vessels, lungs, and blood. Within that scope, research training in nutrition may involve many topics including, for example, - effects of diet on blood lipids and lipoproteins; effects on coronary heart disease morbidity and mortality; the relationship between weight (obesity) and of salt intake in the etiology and treatment of hypertension; effects of maternal diet on neonatal respiratory distress syndrome; of diet; effects of diet on platelet function related to blood clot formation.

F. Please describe and provide budgetary information regarding the NHLBI's programs involving diseases which particularly afflict children.

Answer: Since the enactment of the "National Heart, Blood Vessel, Lung and Blood Act of 1972," the NHLBI has placed greater emphasis on the treatment and on the study of the initiation and progression of illnesses of the heart, lungs and blood during childhood. Childhood is recognized as the crucial time when disease processes may start, and the study of these diseases and their sequelae in the pediatric population is seen as elucidating prevention and control efforts in both children and adults.

Congenital and Rheumatic Heart Diseases

Congenital and rheumatic heart diseases are serious problems which affect both children and adults in the impairment of quality of life, and often cause premature death. Each year 8 out of every 1,000 babies are born with congenital heart defects serious enough to require treatment. Half do not survive to their first birthday. The program in congenital and rheumatic heart diseases seeks to: understand the causes of congenital heart disease, to improve its diagnosis and therapy, to assess the long-term effects of therapy, and to rehabilitate patients with the disease; and obtain a better understanding of the immunological problems associated with rheumatic heart disease.

The Institute is currently supporting approximately 20 laboratories through individual research grants and four additional groups through program project grants for investigations related to congenital heart disease and the development of the cardiovascular system. The effort is focusing on a number of research areas. Of particular interest is the etiology of congenital heart diseases. In this, animal models are being used to better identify causes for congenital malformations of the circulartory system. A number of studies are concerned with the developmental physiology of the cardiovascular system. Studies are determining the effect of cariac sympathetic nerve stimulation and the use of pharmacological agents to examine the development of peripheral vascular responsiveness. These studies could have significant bearing on the care and the treatment of children with cardiac and other diseases.

Another area of research dealing with the adaptation and refinement of diagnostic techniques used in the very young. A development of accurate and reliable non-invasive techniques is of particular importance in the pediatric age group.

Research is also continuing on a surgical treatment of congenital heart defects and to evaluate existing treatment through well-defined followup studies. Refinements in surgical procedures such as hypothermia, cardiopulmonary bypass, prosthetic devices as well as the development of new operative techniques for the more difficult lesions, continue with emphasis on improvement of their use on the neonate and early infancy. Research also continues on the nonsurgical treatment of cardiac disease in children including the transcatheter closure of atrial septal defects, the pharmacologic closure of the patent ductus arteriosis in preterm infants, and the study of age-related differences in response to cardiovascular pharmacological agents.

Several grants are concerned with the study of the pathogenesis of rheumatic carditis. Support for this area of research involving immunological mechanisms is shared with the National Institute of Allergy and Infectious Diseases. Another project is studying the epidemiology of streptococcal infections with the objective of improving preventive regimens. Work on the biochemistry of diseased valves, the structure and function of valves and the evaluation of patients who have had valve repair or replacements is ongoing. In addition, there is research concerned with development of diagnostic techniques, with studies of cardiovascular physiology under various stress conditions, and with solution of problems encountered in cardiovascular surgery which are indirectly related to rheumatic heart disease.

Hypertension

In order to delineate and more fully understand the significance of hypertension in childhood and young adult life, the Institute solicited applications for proposals in this specific area and subsequently awarded 16 grants for the study of the epidemiology of hypertension in the young. Because of the enthusiastic response by highly qualified investigators, it was possible for the Institute to initiate a more effective research program in this area. Studies stress the characteristics of blood pressure in children and the precursors of adult hypertension: (1) the relationship between physiologic measures and personal characteristics and blood pressure; (Such relationships may help explain the course of elevated blood pressure as well as aid in identifying children with elevated pressures.) (2) The role of diet in determining blood pressure levels; (for example, the role of salt intake, and feeding habits, particularly in baby foods has received considerable notice but there is still much controversy about its importance. (3) The extent that cultural patterns, stress, urbanization and similar factors account for differences in blood pressure between various subgroups of the population. (4) The consequences of adolescent hypertension. (5) Studies of children of hypertensive parents.

While some work has been performed indicating familiar clustering of hypertension, it is now known at what ages clustering becomes manifest and whether it is initiated through environmental or genetic factors. The Framingham Offspring Study is studying the children of the Framingham Study Cohort to explore the various familial and genetic associations between family members.

An Institute initiated Task Force on Blood Pressure Control in children recently prepared guidelines for practicing physicians and health care providers involved in school health and other community programs for children.

Arteriosclerosis and Coronary Heart Disease

Specialized Centers of Research in Arteriosclerosis program supports; (1) studies to determine the relationship between risk factors of children of victims of cardiovascular disease and the risk factors of children of healthy persons; (2) epidemiological studies of both black and white pediatric populations; (3) studies of blood pressures and the incidence of hypertension in children; and (4) studies on the influence of dietary cholesterol and blood serum cholesterol. For example, the results of one study indicate that there are approximately four times the number of coronary deaths in the relatives (ages 35 to 60) of children who had high serum cholesterol levels.

The Lipid Research Clinics have an active program dealing with lipids in children. In the LRC Prevalence Study, data on lipid levels from 20,000 children provide the largest assembly of lipid data in this important age group, ages 0 to 19 of different ethnic backgrounds.

Task Force on Prevention and Treatment of Cardiovascular Disease in the Young

The Institute has recently undertaken the comprehensive review of heart disease in childhood through a task force which is assessing the current state of knowledge in this area. It is anticipated that the work of the task force will result in new programs to: assess the role of genetic factors in heart disease; track risk factors through childhood and into adulthood to enable individuals with increased risk to be identified and assisted as early as possible; to improve the prevention, detection and treatment of congenital heart disease; and educate the public and physicians on both congenital and rheumatic heart disease prevention and treatment. This Task Force will report its findings in the summer of 1978.

Respiratory Distress Syndrome

Neonatal Respiratory Distress Syndrome is thought to be caused by immaturity of the lungs, and its incidence can be correlated with the degree of prematurity and by a low birth weight if this is the result of premature delivery of the infant. Since glucocorticoids increase the maturity of lung tissue in fetal animals, administration of these drugs to human mothers is being investigated. A recently initiated, randomized, double-blind, controlled trial will evaluate the effectiveness of corticosteroids administered 24 to 74 hours before birth in decreasing the incidence of NRDS. The trial will also attempt to determine whether such therapy has any adverse short-term or long-term (up to 18 months) effects on the infant.

Although these advances are reflected in a marked reduction of infant mortality, the important challenge for the future is to prevent NRDS, a challenge being addressed through fundamental investigations of lung development and the factors that delay maturity.

Cystic Fibrosis

Since cystic fibrosis is a genetically determined disease, there is great interest in identifying underlying biochemical changes that can be the basis of early detection. One such factor--the ciliary inhibitory factor, which is detected by its effect on ciliary action--continues to be studied. Progress is being made in isolating and characterizing the molecule that produces this effect on cilia. It has been obtained in culture from the cells of parents of cystic fibrosis patients, although the parents are heterozygous for the genetic determinants of the disease. In addition, further research is elucidating the characteristics of the possibly abnormal mucus in cystic fibrosis patients and the factors that cause the abnormality.

Bronchiolitis

The effects of bronchiolitis in infancy on subsequent respiratory disease has been examined in a group of children and adolescents. Randomly enrolled in the SCOR program the subjects selected are non-smokers with a history of croup. The Study will determine if there is an increase in prevalence of lung function abnormalities in adults who have a history of acute childhood lung diseases.

Pediatric Pulmonary Diseases SCORs

Specialized Centers of Research in Pediatric Pulmonary Diseases are concerned with neonatal respiratory distress syndrome (hyaline membrane disease) and cystic fibrosis as well as other obstructive lung diseases in children, such as bronchiolitis. Research is being conducted on the etiology and pathogenesis of these diseases as well as on assessment of present modes of management and new and innovative approaches to therapy. Some Centers are pursuing prospective studies of the effects of diseases in childhood on chronic lung diseases in the adult.

Sickle Cell Disease

The NHLBI supports a variety of activities aimed at reducing the frequency, morbidity, and mortality of sickle cell disease through research and improved diagnosis, treatment, and education activities. These activities comprise a coordinated program of: basic and clinical research: Comprehensive Sickle Cell Centers; Screening and Education Clinics; education services; and a hemoglobinopathy training program.

The biomedical research program has contributed to the advancement of our understanding of sickle cell disease through molecular, cellular, tissue, and organ studies. We can now detect sickle cell disease in the newborn and soon will be able, with the refinement of a new fetoscope, to advance to prenatal detection. Important new research projects include an attempt to understand and clarify the molecular conformation of sickle hemoglobin and its interactions in the oxy- and deoxy-states; the study of cell membrane changes during sickling; the augmentation of fetal hemoglobin in red blood cells; investigation of viscosity and flow properties; and the role of clotting factors in the painful crisis.

Hemophilia

Hemophilia is an inherited, life-long disease which is extremely debilitating and limits median life expectancy to about 25 years. Much research has been done on the genetics and molecular biology of the disease. It is now known that the hemorrhagic tendency results from the patients's inability to synthesize the functional form of a protein essential for completion of the intrinsic clotting system. While improvement in the clinical condition of the hemophilia patient over the last two decades represents an important advance in the battle against this disease, more recent concerns relate to possible complications of hemophilia therapy. Recently, the National Heart, Lung, and Blood Institute co-sponsored, with the Bureau of Biologics, Food and Drug Administration, a two-day workshop on Unsolved Therapeutic Problems in Hemophilia.

Cooleys Anemia

Thalassemia major (Cooleys anemia) is an inherited hemolytic anemia in which the erythroid cells fail to synthesize normal amounts of hemoglobin. Chronic transfusion therapy, the accepted treatment for this disorder, results in alleviation of the anemia and the excessive erythropoiesis but increases the iron accumulation.

The National Heart, Lung, and Blood Institute currently supports research under an RFA entitled "Improved Methods for the Clinical Management of Thalassemia". Several observations of significance have resulted from these funded studies to date. It has been confirmed that long-term parenteral iron chelation therapy with desferrioxamine (Desferal$^{(R)}$) can place patients in negative iron balance. Children maintained on a transfusion regimen from early diagnosis can live essentially normal lives without the physical, endocrine, and cardiac dysfunction characteristic of the disease.

6. Please describe and give the current status of the drug trials supported by NHLBI.

Answer: Clinical trials are a major and critical component of the NHLBI program. The clinical trial provides the definitive validation step in testing the efficacy of preventive and treatment regimens before they are introduced into practice. They are the vital link between clinical investigation which develops the concepts for testing through clinical trials and the health care system in which the regimens are applied. The Institute investment in clinical trials now amounts to about 15% of its extramural budget (over $50 million for fiscal 1977). The institute's trials range in objective from trials of preventive regimens to trials that compare existing treatments; and range in scope from experiments that may involve as few as 200 subjects in which the trial is conducted in one or two clinical centers to trials involving more than 12,000 subjects conducted in centers across the country. Because of the large costs of clinical trials which can amount to $2,000 per patient per year, and over $100 million for the entire clinical trial, it is imperative that the Institute allocate its resources to problems of critical research and health care need. To insure the appropriate allocation of its resources, the Institute has developed a clinical trials management process which conceives of the trial as divided into four distinct phases: Phase 0 - Initiation; Phase 1 - Planning; Phase 2 - Recruitment and Intervention; andPhase 3 - Analysis and Dissemination. Separating each phase is a crucial decision point at which the Institute determines whether to commit resources to the next phase. The process is used to assure that the trial is within the National Heart, Lung, and Blood Institute's purview and that the scientific basis for the trial and the potential impact of the trial on health care and research are appropriate for the resources required.

A number of the trials conducted by the National Heart, Lung, and Blood Institute do not involve drugs in any phase of the intervention. These trials are not included in the description below. Other trials directly involve drugs and are included below, while still other trials involve drugs or biologicals in an indirect way. These are so indicated in the trial descriptions. The descriptions all represent current trials.

The following two trials are both related to drug regimens for the prevention of death in patients who have had a myocardial infarction. The risk of death is much higher for such patients than for the general public. Sudden cardiac deaths take between 300 and 400 thousand lives each year.

Aspirin-Myocardial Infarction Study (AMIS)

Objective: To determine whether the daily administration of 1 gram of aspirin to individuals with a documented myocardial infarction will result in a significant reduction in mortality, the intervention is to extend over a three-year period.

Current Status: The trial is now in Phase 2, Recruitment-Intervention Phase. Recruitment has resulted in 4,524 patients enrolled in 30 clinical centers.

Beta-Blocker Heart Attack Trial (BHAT)

Objective: To determine whether or not the regular administration of propranolol (a beta-blocking agent) to people who have had at least one documented myocardial infarction will result in a significant reduction in mortality from all causes over the follow-up period of two years.

Current Status: The trial is currently in the planning phase (phase 1). Contracts have been awarded to 32 clinical centers, an EKG Center, a central laboratory and a coordinating center. The trial design consists of 4,200 patients in a double-blind clinical trial, each patient to enter within 14 days after the onset of the acute event. One-half of the patients will be randomly assigned to propranolol and one-half to placebo.

The following trials are aimed at the primary prevention of cardiovascular disease. Based on the previous identification of the critical risk factors for developing coronary heart disease, these trials are intervening through drugs alone and through drugs in combination with behavioral intervention. These trials hold the promise of validating preventive regimens that could significantly reduce the toll of cardiovascular disease, now responsible for over 50% of the Nation's deaths per year.

Lipid Research Clinics Coronary Primary Prevention Trial (CPPT)

Objective: To determine if reduction of cholesterol by cholestyramine therapy will significantly lower the atherosclerotic coronary heart disease rate in a group of hypercholesterolemic, but otherwise healthy men.

Current Status: The trial is now in phase 2 with 3,810 subjects in 12 clinical centers. The total period of intervention for each patient is expected to last seven years until the trial completion now scheduled for 1983.

Multiple Risk Factor Intervention Trial for the Prevention of Coronary Heart Disease (MRFIT)

Objective: For a group of men at high risk of death from coronary heart disease, this trial will assess whether a special intervention program to lower serum cholesterol, reduce blood pressure, and eliminate cigarette smoking will result in a significant reduction in mortality from coronary heart disease.

Current Status: This trial involves some 12,000 male patients ages 35 to 57. The trial is underway at 20 clinical sites across the country. Recruitment was completed in 1976 and intervention is expected to last into 1982.

NHLBI Type II Coronary Intervention Study

Objective: The primary objective of this trial is to determine whether lowering of cholesterol with cholestyramine in a population with Type II hyperlipidemia can lead to a decreased rate of progression (a regression) of coronary artery disease as demonstrated by death, myocardial infarction, or progression of disease on angiography.

Current Status. The trial is currently in its five-year intervention phase with final results expected within three years.

Hypertension Detection and Follow-up Program (HDFP)

Objective: To determine the effectiveness of antihypertensive therapy in reducing morbidity and mortality from hypertension in a wide spectrum of persons with elevated blood pressure in 14 communities. Hypertension is one of the major risk factors for cardiovascular disease.

Current Status: The trial is currently in the Intervention Phase. More than 11,300 hypertensive participants have been randomized to either stepped care or regular care in the 14 participating centers. Stepped Care is that mode of treatment in HDFP clinics in which a diuretic is given and additional antihypertensive agents are added in a time-structured stepwise fashion until goal blood pressure is achieved. Referred care represents referral to private physicians and other community sources of care. Of the 5,485 Stepped Care participants, 3,042 or 55.5% are currently active and at or below goal. 70.5% of the currently active Stepped Care participants are at goal. The trial is in its fourth year of a scheduled five-year intervention.

The following trial is aimed at the critical problem of reducing or limiting the damage caused by a myocardial infarction once it has occurred.

Multicenter Investigation of Limitation of Infarct Size (MILIS)

Objective: This trial will assess the ability of two separate therapeutic interventions, propranolol and hyaluronidase, to limit the ultimate size of an acute myocardial infarction. A secondary objective is to assess the influence of these therapies upon ventricular function and morbidity following myocardial infarction.

Current Status: The trial is currently in the planning phase. Patient recruitment has not yet begun. In September 1977 contracts were awarded to three clinical centers and one data coordinating center for a coordinated planning effort. Commitment to the trial must await analysis of a detailed trial protocol.

The next two trials both compare medical treatment including drug management for various coronary heart disease problems against surgical management.

Unstable Angina Pectoris Trial

Objective: The purpose of this drug trial was to compare the efficacy of medical or surgical (coronary artery bypass graft) therapy as regards survival and quality of life in patients with unstable angina and requisite coronary anatomy as defined by angiography.

Current Status: The trial is about to move into Phase 3 (analysis and data dissemination). From 1972 through 1976, 288 patients were entered into this randomized clinical trial. One hundred forty-seven patients received intensive pharmacological medical therapy and 141 comparable patients underwent coronary artery bypass surgery. A preliminary analysis of the data indicated that patients presenting with unstable angina may be safely treated with careful intensive pharmacologic therapy. Those with persistent pain may be studied by coronary angiography and those patients with left main coronary artery obstruction, and continued intractable pain, may require surgery. Otherwise, prophylactic surgery to prevent a myocardial infarction or death is not necessary.

Coronary Artery Surgery Study (CASS)

Objective: The purpose of the major study of coronary artery surgery is to compare surgical treatment with medical management in patients with coronary artery disease, with or without stable angina pectoris.

Current Status: The trial is currently in the Recruitment-Intervention Phase. Approximately 450 patients have been entered into the trial which has a goal of 700 patients. Recruitment will continue through June 1978, with followup to extend for five years.

The following trial concerns the important problem of neonatal respiratory distress syndrome which is one of the leading causes of death and disability in the newborn. Each year some 50,000 cases occur. The trial involves drug therapy to prevent the occurrence.

Prevention of Neonatal Respiratory Distress Syndrome with Antenatal Steroid Administration

Objective: The primary objective of this trial is to determine the effect of corticosteroids administered 24 to 72 hours before parturition, on the incidence of neonatal respiratory distress syndrome; and to determine whether the therapy has any adverse short or long-term (up to 18 months) effects on the infant.

Current Status: The trial is in the Recruitment-Intervention Phase. Six clinical centers and one coordinating center are cooperating in the trial. Followup will continue for eighteen months following entrance of the last patient in 1979. A total of 600 patients will be enrolled.

The following trial, conducted by the NHLBI, Intramural Division, is concerned with fibrotic lung disorders which represent 15 to 20% of the non-infectious disorders of the lungs. This chronic devastating illness results in death an average of four to five years after onset of symptoms.

Diffuse Fibrotic Lung Disease: A Correlative Study of the Etiology, Pathophysiology and Therapy

Objective: The objective of this trial is to determine the effects of azathioprine vs. cortisone in the therapy of idiopathic pulmonary fibrosis.

Current Status: The trial is currently in the Intervention Phase. Thirty patients have been enrolled and the trial is scheduled for completion in 1978.

The next several trials all deal with problems related to blood diseases or blood resources, areas within the NHLBI mandate.

Iron Chelation Therapy with Deferrioxamine

Objective: The objective of this trial is to determine the therapeutic effect of deferrioxamine in thalassemic patients with iron-overload caused by multiple blood transfusions.

Current Status: This trial is currently in the Intervention Phase. Various iron chelators, with an emphasis on deferrioxamine, are being evaluated in patients at five clinical centers. The trial involves some 125 patients, and will be completed in 1979.

Evaluation of Chronic Chelation Therapy for the Treatment of Transfusional Hemosiderosis

Objective: This trial will evaluate the effect of iron removal by desferrioxamine administered chronically by intramuscular injection or continuous subcutaneous infusion, on the organ dysfunction occurring in iron overloaded patients.

Current Status: The trial, which is being conducted by the Intramural Division of NHLBI, is currently in the Intervention Phase. Detailed endocrinological evaluation is performed prior to and at regular intervals during chelation therapy. These studies include assessment of pituitary function by measurement of TSH and gonadotropins after administration of appropriate releasing factors. Cardiac function is also assessed.

Granulocytes: Studies of Collection, Function, and Transfusion

Objective: The purpose of this trial is to determine whether prophylactic and therapeutic use of granulocyte transfusions in patients undergoing chemotherapy for leukemia will reduce infections.

Current Status: The trial is being conducted at four clinical centers and is currently in the Recruitment-Intervention Phase. Protocol design to evaluate the efficacy of prophylactic granulocyte transfusions was completed at the close of 1977. The protocol for the therapeutic trials has not yet been finalized. If final protocols are acceptable, it is anticipated that 250 patients will be included in the study.

Cooperative Study of Factor VIII Inhibitors

Objective: The primary objective of this trial is to evaluate the therapeutic value of Factor VIII, a biological, in patients with hemophilia A.

Current Status: This trial is currently in the Recruitment-Intervention Phase. Of the more than 1,300 patients entered into the trial at the 10 clinical centers, approximately 16[illegible] have been classified as inhibitors patients and 50[illegible] of these have been treated by infusions of Factor IX concentrate, and intermittent or continuous infusions of Factor VIII concentrate. The trial will continue through 1978.

Interruption of Maternal to Infant Transmission of Hepatitis B by Means of Hepatitis B Immune Globulin

Objective: This trial will evaluate whether the biological, hepatitis B immune globulin, with a high level of antibody against the hepatitis B antigen would be capable of interrupting maternal-fetal transmission of hepatitis B virus, the single most important route of hepatitis spread in the entire Third World.

Current Status: The trial is in the Recruitment-Intervention Phase. To date, 205 babies have been accepted into the study which is actually being conducted in Taiwan through a contract to the Community Blood Council of Greater New York. Only these babies born of mothers who had HBsAg complement fixation titers of 1:8 or greater were included in these studies. At birth, blood was obtained from the mothers and cord blood from the infants. Follow-up bloods were obtained from both the mother and baby when the infant was 1, 3, 6, and 12 months of age.

H. Please indicate the types of personnel that NHLBI has difficulty in recruiting for permanent positions if this is a problem.

Answer: Recruitment has been a serious problem for physicians of all levels. It has been particularly severe for those at intermediate and senior levels. Salaries are simply not competitive even with academia, let alone with the private practice of medicine.

Physicians knowledgeable in clinical investigation and in the area of prevention, control, and education are particularly in demand and sought by the Institute. At the most senior level, the Institute is currently searching for a Director of the Division of Blood Diseases and Resources and is having serious problems in recruitment in very large part because of financial limitations. Similarly, the Institute has not been able to fill the position of Assistant Director for Prevention, Control, and Education, in part because of a shortage of experts in this area, and particularly because of the poor competitive position of the Institute with respect to compensation.

IV. National Research Service Awards

A. What are the current shortage categories and surplus categories of research personnel and what is the extent of these shortages and/or surpluses? Specifically, what are the needs for personnel in the fields of epidemiology, toxicology and veterinary pathology?

In its 1977 report the National Academy of Sciences Committee on National Needs for Biomedical and Behavioral Research Personnel reported that it had attempted to identify priority fields for special emphasis for research training. It concluded, however, that in view of the extent to which field switching occurs (that is, individuals trained in one field of biomedical science then work in "another" field) that the identification of specific fields for priority consideration would be extremely difficult, and perhaps unwise. The two exceptions to this conclusion were the fields of biomathematics/biostatistics and epidemiology, which they deemed to be clearly in short supply.

With regard to the behavioral sciences, the Committee felt that there may be a surplus in the near future and therefore recommended a reduction in predoctoral training programs and a shift in emphasis to postdoctoral training, since it believes that problems of mental health and human development present fundamental research issues for which postdoctoral training is likely to be necessary.

With regard to clinical investigators, the NAS report suggests that "the available data substantiates the impression of a continued strong demand for clinical investigators and a diminishing amount of research activity on the part of the physician population." They note that from 1971 through 1975 the number of physicians who reported research as their primary activity has declined by a little more than 7% a year while at the same time indicators of demand for clinical investigators continue to move upward.

Independently of the Academy, the NIH sampled the job market for doctoral biomedical scientists in May 1975 and followed up the responses in October. The survey indicated that in almost all fields requiring researchers with health professional doctorates (M.D., D.V.M., and D.D.S) these individuals were in short supply. In five clinical fields studied in detail (anethesiology, medicine, neurology, opthalmology, pediatrics) an estimated 965 scientists completed their training and were placed in positions. However, in the October report an estimated 358 openings had not yet been filled and only 17 scientists who had completed training were still seeking jobs.

The survey suggested that the market for Ph.D.'s was also characterized by excess demand. In seven basic science fields studied in detail, an estimated total of 540 positions was open in October of 1975 but only 73 individuals who had completed their training were available to fill them. The only field in which there seemed to be a clear excess of individuals seeking positions over the number of positions available was zoology, a field not ordinarily supported by NIH programs.

The 1975 market survey results are consistent with data showing that M.D.'s and Ph.D.'s preparing for research careers by taking postdoctoral fellowships do so at some personnel cost. They can not expect to recover the lost income and costs incured for postdoctoral study through higher incomes earned in subsequent years. The "economic rate of return" to such postdoctoral training was found to be greatly negative for M.D.'s and nil for Ph.D.'s.

The market survey was repeated in 1977 but the data are being analyzed and results are not yet available.

The 1975 sample survey did not provide evidence at the fine detail needed to judge the market situation in the fields of epidemiology, toxicology, and veterinary pathology. We have already noted the conclusions of the National Academy of Sciences study that epidemiology, at least, is a field which is in short supply. The need for toxicologists was explored specifically in a workshop sponsored by the National Institute of Environmental Health Sciences, the Chemical Industry Institute of Toxicology and the Environmental Protection Agency, held in Annapolis in 1977. That workshop estimated that there were some 5,000 working toxicologists in the country. It anticipated a need for 1,000 more and an annual attrition rate of approximately 200.

We lack specific estimates for veterinary pathology. But in view of the stimulus of legislation dealing with laboratory practices and animal care requirements, and of expanded research efforts in environmental medicine, toxicology, and carcinogenesis, an increased need for veterinary pathologists may be anticipated.

B. What is the current status of the research and teaching job market for biomedical research personnel (and specifically NRSA recipients if these data are available)?

In its 1977 report the National Academy of Sciences published the findings of a sample survey of 1971-1975 Ph.D. recipients. The principal findings reported for the biomedical sciences were that 94% of the respondents held regular full time positions or postdoctoral appointments, and less than 2% were unemployed and seeking jobs. Seventy percent were employed by educational institutions and almost 90% devoted at least some time to research. Approximately 20% of all of the respondents held postdoctoral appointments. Approximately 6% of the individuals who had received their Ph.D. in 1971, 1972 or 1973 held postdoctoral appointments at the time of the survey and indicated that they had prolonged these appointments because of difficulty in finding suitable employment. Between 1971 and 1974 the proportion of graduating Ph.D.'s who accepted postdoctoral appointments within a year after earning their doctorate remained fairly steady, between 53 and 56%. In 1975 the proportion jumped dramatically to 62%. Despite the increase, however, there was no change in the reasons given for undertaking postdoctoral training. In each year, approximately 62% of those taking postdoctoral appointments indicated that they were seeking additional research experience, some 15% noted that they were switching to another field of research and approximately 13% reported inability to find suitable employment. On the basis of the data in this survey the NAS expresses concern about what it sees as a growing tendency to take postdoctoral appointments and other positions which are not considered to be on a tenure track in universities.

In the behavioral sciences the survey indicated that some 88% of the respondents held full time positions, that only 3% held postdoctoral appointments and that some 2% were seeking employment. Despite a significant amount of switching between the field of training and the field of employment, most of the recent graduates judge themselves to be employed in positions appropriate to their training.

The NAS unemployment rate of something less than 2% may well be largely explainable by the usual frictions in the market. The survey undertaken by an NIH contractor, mentioned in question A, suggests that demand generally exceeds supply in the job market for doctoral biomedical scientists although there may be a few fields in which this is not so. The major difference between the NIH survey and the NAS survey is in the interpretation of the significance of a postdoctoral appointment. The NAS committee sees a progressive growth in postdoctoral training among new Ph.D.'s as an indication of market weakness, believing that these people are being forced into fellowships for the lack of better, more permanent jobs. Alternatively one may suggest that like other training activities the added training involved in a postdoctoral appointment insures a better qualified cadre of researchers and teachers in the field. Additionally, in view of the current realities of the market place it is not entirely clear that the availability of tenure track positions is the appropriate criterion in terms of which to assess the demand for biomedical and behavioral research scientists.

Specific data for NRSA recipients is not available.

C. As the old "section 301" research training programs are phased out, are there any research training programs which cannot be funded under the "section 472" NRSA authority? Are there any such research training programs which can be funded under NRSA authority but are otherwise inappropriate for funding under that authority because of its service/monetary payback requirements? What are the major differences you have experienced between administering research training programs under section 301 and the NRSA authority? Do you believe that the service payback requirements of section 472 are discouraging young people from applying for NRSA's? Are you having any difficulty administering the payback portions of the statute? Are there any changes in the provisions which you feel would improve it? Do you believe the payback provision is necessary to assure that award recipients engage in research careers upon completion of their training? Should Congress eliminate the payback requirement?

This question includes at least five questions. It is presented in its entirety here, as given, and the individual elements are repeated below, together with the responses.

- As the old "section 301" research training programs are phased out, are there any research training programs which cannot be funded under the "section 472" NRSA authority? Are there any such research training programs which can be funded under NRSA authority but are otherwise inappropriate for funding under that authority because of its service/monetary payback requirements?

Short term training (3 months or less for intensive research experience, courses, seminars, introductory research experience or other similar activities) was commonly supported under the old training authority but is exceptional under NRSA. Most of the Institutes would like to be able to provide for such support, but have reservations about doing it under present authorities. NHLBI has a research development summer program in hypertension for minority investigators and the NICHD supports a summer course for training in embryology at Woods Hole, Massachusetts. There is particular interest in some of the Institutes in providing for a research opportunity for medical and dental students in off quarters as a way of interesting them in the long term possibilities of becoming involved in research. The major deterrent to using the NRSA authority for such programs is the payback requirement. The Institutes believe that since essentially all of the students in such programs will be supported on a one time, short term basis, the administrative cost of tracing them for two or more years beyond their enrollment in these programs, for payback purposes, would be grossly disproportionate to the benefits. There is an additional complication that although many of these students may have completed their NRSA training they may not have completed their fundamental training in medicine, dentistry or science within the time required for beginning payback activity.

Another situation for which NRSA is inappropriate is support for the medical student who shows aptitude for research and, based on recommendations of his or her professors, drops out of the medical school curriculum and spends a year in research before returning to medical school. This exposure to research is a very important factor in career decisions after medical school is completed and has been an effective recruitment mechanism for routing highly competent individuals into research. Under NRSA, the individual who undertakes such an initial research involvement but later does not pursue research is obligated to repay the NRSA obligation despite the fact that he or she has given up a year of income as a physician. Although no data are available, the current authority tends to make research training a less attractive option--particularly for the medical student who has the option of substantial salaries in private practice.

ADAMHA also has reservations about providing support for short-term training under NRSA because of the payback requirements and the requirement for support of training in specific areas of need. In addition, a small number of projects funded by ADAMHA under previous training authority cannot be funded under NRSA since they provided combined training for clinical and research careers. No administrative distinction was made between these activities prior to the NRSA authority since the agency had an undifferentiated authority in section 303 of the Public Health Service Act, which allowed the support of grants for such combined programs. As a result of the NRSA requirement, a clear demarcation is now made between clinical and research training grant support. For those institutions which had the "old" combined programs, separate applications are now required.

- What are the major differences you have experienced between administering research training programs under section 301 and the NRSA authority?

The NRSA, because of its requirement for a study by the National Academy of Sciences and by the addition of the payback provision, has required much greater emphasis on planning and coordination of training activities across both the NIH and ADAMHA than was previously the case. One immediate effect has been the concentration of attention on the problem of improving data collection regarding training, both on a national level and within the agencies.

The payback requirement has imposed a major new administrative workload on the agencies. In addition to the work required to develop a system for monitoring payback, there are administrative burdens connected with establishing and maintaining payback files on all NRSA awardees. The full impact of the burden of tracing former awardees has not yet been felt because the first major cohort of individuals supported under NRSA is just reaching the point where payback will be required.

Another undesirable effect of the payback requirement is that it places NIH and ADAMHA in the new and somewhat awkward position of "policing" the activities of private persons who are no longer receiving Federal funds. As noted above, the impact of this role has not yet been felt. However, such monitoring represents a significant departure from usual administration of extramural programs.

In addition, the management of training programs has become more complex and to some extent more rigid. Some of the flexibility which is indispensable for the most effective operation of training programs for individuals has been lost. On one hand, the NRSA authority and its attendant payback obligation has probably made it highly desirable that potential applicants be fairly sure about their intention to pursue research careers before they apply for support. At the same time, the individual with excellent potential who is not sure research is for him or her might decide against pursuing this alternative because the payback burden seems too onerous. In addition, the payback obligation tends to "lock in" the awardees. For the majority who are successful in the research setting, this is not a significant problem. They complete their training and go on to research and teaching. There is, however, a small proportion of individuals who for a variety of reasons do not fit this pattern. They may find they are not suited to research careers; they may encounter personal or financial problems which cause them to drop out of the research track; it may turn out that they are mediocre scientists and their career goals change. Few, if any, of the individuals in this group have large financial resources. If they have not completed their training, they are not equipped to find a job which would qualify as service payback, and they cannot afford to pay back the monetary debt. If they have completed it, they are forced to seek research or teaching positions even if not well fitted for them. In the latter case, public purposes are not, in fact, well served.

Another problem has arisen from efforts to administer the program fairly and uniformly. The regulations state, for example, that only full-time training is authorized because monitoring part-time training in a uniform way would be extremely burdensome, if not impossible. Yet, this excludes, for example, the woman who would return to research training part-time after the birth of a child. Also, although it is a simple matter to provide for interruption of research training for other activities, provision for the possibility that an individual might undertake some activity that would count as payback service in the interim has proven extremely difficult to administer.

o Do you believe that the service payback requirements of section 472 are discouraging young people from applying for NRSA's?

There have been some anecdotal reports that individuals have been discouraged from applying for NRSA support because of payback requirements, but we do not yet have specific evidence which will enable us to document whether or not payback is having a discouraging effect. The number of applications for individual fellowships has declined, but the considerably lengthened review cycle associated with NRSA may be a contributing factor. The 1977 report of the National Academy of Sciences points out that there are numerous deterrents to the entry of young physicians, in particular, into research. Social, economic and professional factors are cited which may be expected to interact in varied ways with the payback provision, particularly for the individual who is considering NRSA support as a means of undertaking an initial research experience, without being certain beforehand that he or she wants to go on to a full-scale research career.

The recent Internal Revenue Service ruling that the payback requirement provides a basis for concluding that NRSA's are taxable is relevant also. It is not clear whether this ruling contributes to discouraging individuals from seeking NRSA support, but it does make the awards less attractive.

- Are you having any difficulty administering the payback portions of the statute? Are there any changes in the provisions which you feel would improve it?

The problem of administrating payback for short-term training programs has already been mentioned. Certainly, providing for three-month short-term training programs not under payback would enable NIH to reinstate these useful and important programs.

In addition, there is a major problem associated with individuals who discontinue training before completing it. This affects predoctorals who do not complete the Ph.D. as well as postdoctoral health professionals who, after a period of training, either find that they are not well suited for research or who decide upon a change in career plans. Although in most cases individuals do and should engage in payback, there are some few for whom waiver should be allowed and who would currently be ineligible because of the restrictive manner in which the waiver provision is worded in the law. Although no one has, as yet, applied for a waiver, preliminary discussions have indicated a potential problem because of this restrictive language. Specifically, it is suggested, in anticipation of future problems, that (1) there be a slight modification of the language of section 472(c)(5)(B) by deleting the word "extreme" before the word "hardship", and (2) the Committee provide additional language in its report indicating the intent of Congress that the Secretary be granted some flexibility in determining appropriate use of waiver. In the absence of such clarification from the Congress, the NIH, on the advice of General Counsel, must interpret the current provision in a most restrictive manner. We might anticipate, for example, the following hypothetical case: A person in his early twenties accepted an NRSA and entered upon his first year of graduate work in biomedical science. After his initial year in this endeavor, he finds that he is unsuited for research, either because he does not find a research career compatible with his nature, or because he does not have the ability. He drops out and perhaps takes a non-research job paying $8,000 or $9,000 a year. He has a wife and two children. It would be useful to have some guidance from the Congress as to whether or not this situation constitutes a hardship case. In the absence of such clarification, and on the plain face of the words in the law, we are advised that such a case would not. The NIH would then find itself in a most unenviable position vis-a-vis such individual, perhaps forcing them into bankruptcy.

Another situation could be envisioned in which individuals could pay, but under severe financial burden. It would be useful to have something in the legislative history of this provision to indicate that the Congress intends to allow the Secretary the necessary flexibility to determine the particular financial and other circumstances which might qualify an individual to receive a waiver. Under no circumstances, of course, would this change be used as a loophole in which to excuse large numbers of recipients from this obligation. However, in the case of persons with limited income and little savings, who theoretically could repay but might have to do so by borrowing funds, it would be helpful to have more evidence of Congressional intent in the legislative history.

- o Do you believe the payback provision is necessary to assure that award recipients engage in research careers upon completion of their training? Should Congress eliminate the payback requirement?

The principal guarantees of program effectiveness are rigorous selection and thorough training. For Ph.D.'s, careers in research and teaching represent the normal pattern, and it seems unlikely that the payback provision will increase the frequency with which such careers are sought. Thus, several years ago, the National Academy of Sciences studied NIH-funded trainees and fellows who had received their bachelor's degrees between 1956 and 1960 and then completed work for the Ph.D. Those on whom information was available were analyzed in two groups--support only through the Ph.D. and postdoctoral support. As of 1968-1970, of those who received only pre-Ph.D. support, 91% were involved in research or teaching as their primary activity and 73% were working in a university or medical school. Of those who had had postdoctoral support, 96% were in research or teaching and 82% were in a university or medical school. This was before NRSA and without the requirement for payback.

For the medical school graduate, however, there is reason to believe that the payback requirement acts as a deterrent to continued training for some potential candidates who are uncertain of their long-term interest in research. On the basis of their clinical skills, M.D.'s can receive academic appointments without specific research training--so they may not bother taking it. The service obligation of the NRSA only serves to make the research training alternative even less attractive.

We recognize the desirability of having a device for ensuring that public expectations for the use of Federal research training dollars are met. However, it is not possible to make an unequivocal statement on the extent to which the payback provision supports that purpose.

D. How many requests from NRSA recipients has the Department received under section 472(c)(1)(C) of the PHSA for authorization to engage in a "health-related activity" in lieu of engaging in the "health research or teaching activity" required under other provisions of section 472 of such Act? How many of these requests has the Department approved and/or rejected? Please provide the relevant regulations, application forms, or other appropriate information.

As of January 1978, NIH has considered 13 such requests and all but 2 of them have been resolved. Most of these requests came from individuals who had decided for various reasons against continuing their studies. For individuals who had been enrolled in Ph.D. programs NIH has approved alternative service as technicians, administrators, and program analysts in health related activities. A major problem in the two requests still pending has been that of making the preliminary determination that "no suitable research and teaching position" is available for the individual. In an attempt to clarify the situation for the future, a memorandum dealing with alternative service payback was developed and distributed in August 1977 to the approximately 150 professional degree holders who, as of July 1977, had completed NRSA supported training, but had not yet completed the service requirement. A copy of the memorandum is attached. In addition to describing the several types of alternative service that could be undertaken by professional degree holders, the memorandum requested that interested individuals advise the agency of their interest and only one such response has been received. Copies of relevant regulations and forms are also attached.

ADAMHA has had five requests from former awardees for authorization to engage in health related activities in lieu of health research or teaching. The final decision in each of these cases is still pending.

E. How many requests from NRSA recipients has the Department received under section 472(c)(5)(B) of the PHSA for waiver or suspension of service or monetary obligations due to impossibility, hardships, or inequity? How many of these requests has the Department approved and/or rejected? Please provide the relevant regulations, applications forms, or other appropriate information.

Neither the NIH nor ADAMHA has had any requests for such a waiver. Two obligations were cancelled by NIMH and four by NIH due to the deaths of the recipients.

The primary reason that there have been no requests for waiver is that while over 2,400 recipients have now completed their NRSA training, they have two years to commit themselves to payback service or monetary repayment. In short, there is as yet, little factual information by which to judge this aspect of the program and we are, thus, still at the conjecture stage (see answer to Question C).

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

MEMORANDUM

TO: Individuals holding health professional degrees who have recently terminated support as fellows under the National Research Service Award programs (NRSA).

FROM: Acting Research Manpower Officer, NIH

SUBJECT: Preliminary information on alternate service options. A request for expression of interest from terminated fellows who are considering these for payback service.

Background: The regulations governing service, payback, and recovery requirements of NRSA programs identify post-fellowship activities of two main types as acceptable service (§66.110(a)(1) and (2), see attached copy). Of these the second, here designated the alternative service options, refers to certain actions by the Secretary and to specific programs. This memorandum provides preliminary information on these two subjects, and requests of individuals desiring more detailed information as it become available, to notify this office of their interest.

Preliminary Information:

1. Paragraph (a)(2) refers to two actions by the Secretary, the one a determination that there are no suitable research or teaching positions available to the individual, the other an authorization to engage in one of the alternative services described in subparagraphs (i), (ii), and (iii). Authority for the first of these is delegated to the awarding Institute; the determination will be made on the individual's representation as set forth in a letter to the Institute Director. The letter should address the following: the purposes in mind in undertaking the research training, the extent to which the training contributed to these purposes, and the steps taken on completion of training to seek a research or teaching position, or the reasons for deciding against this course. Authority for the second action by the Secretary is delegated to offices where authorizations governing individual service programs are made. Summary information on these is given below.

2. Summary information on the three alternative service options:

Service as a member of the National Health Service Corps:

This program is administered by the Bureau of Community Health Services of the Health Services Administration. Through this program health services are provided in geographic areas of need, and also for the Indian Health Service and for prisons. Assignments are made on a matching of applications from those with service obligations with defined needs. The matching process for positions to take effect July 1, 1978 will begin in late September, 1977. NIH will forward to former NRSA fellows who express an interest in the alternate service options additional program information and an application form.

Service through private practice in his or her specialty in a geographic area designated by the Secretary as requiring that specialty:

The Health Manpower Act of 1976 effected substantive changes in the designation of these areas. Implementation is the responsibility of the Health Resources Administration. The first list of shortage areas is scheduled for publication this fall. NIH will forward to former NRSA fellows who express an interest in the alternate service options additional information on the designated areas as this becomes available.

Service in his or her specialty for a health maintenance organization:

This program is located in the Bureau of Health Services of the Health Services Administration. Primarily a granting agency to stimulate development of prepaid comprehensive health maintenance organizations, this agency does not have a direct role in their staffing. NIH will forward to former NRSA fellows who express an interest in the alternate service options a list of HMO's that meet the specifications referred to in the NRSA regulations.

3. The next step for those interested in receiving further information about alternate service options:

Interested individuals should forward to this office a letter of request; the letter should include your name, mailing address, and identifying number of NRSA support (individual or institutional fellowship number). A franked return envelope is enclosed.

4. General

a. Inquiries: Until arrangements for formal liaison with the several HEW offices have been completed, questions about these programs should be directed to this office.

b. Timing: Where delays in providing this information to terminated fellows preclude timely arrangements for alternate service, individuals may request a waiver to allow delay of starting date beyond the two-year limit.

F. Should the NRSA service payback provisions be amended to permit an NRSA recipient to meet his or her obligation by engaging in "health research activities outside traditional academic employment (upon application to and approval by the Secretary") or comparable language?

It is the belief both of the NIH and ADAMHA that health research activities outside of traditional academic employment are presently authorized. Research in the pharmaceutical industry may be cited as an example. In general, it is the nature of the research and not the setting that covers the determination. It is clear from a review of the needs generated by recent legislation such as the Toxic Substances Control Act that professional toxicologists will be needed to meet the requirements of regulatory agencies and industry, as well as those generated in more traditional research settings. Similar concerns are encountered in planning for epidemiologists, statisticians and veterinary pathologists. If payback for such individuals in non-traditional settings is perceived as presenting problems it may be desirable that the situation be clarified in report language.

Another area in which the flexibility of the Secretary to operate the NRSA program most efficiently could be enhanced is deletion of the phrase "if the Secretary determines that there are no suitable health research or teaching positions available to such individual" in subsection (c) of section 472. In a practical sense the Secretary cannot realistically determine that no such positions are available. While the Congressional intent is clear that research or teaching positions are the preferred manner of payback, the practical problems raised by this phrase in the statute are many and seem unnecessary in view of the fact that past recipients do go into research or teaching after their training.

C. Has there been a decline in the number of physicians and other clinical investigators who apply for research training support under the NRSA authority? Has there been a decline in the number of professional graduates who apply for such support? If so, what is the extent of this decline and to what factors do you attribute this decline?

Yes, there has been a decline which is summarized in the attached table. The decline started before the enactment of NRSA, but has been accentuated since then. Between 1970 and 1974, the year in which NRSA was enacted, the total number of trainees in NIH funded research training programs declined by 20%, the total number of postdoctorals declined by 13%, but the total number of trainees with health professional degreees, most of whom are M.D.'s, declined by 26%. Between 1974 and 1976, the last year for which complete data are available, the total number of trainees went down by 24%, all postdoctorals went down by the same amount, but health professionals went down by 46%. The same data can be put in another way. In 1970, health professionals, again, largely M.D.'s, represented 27% of all trainees and 66% of all postdoctorals. By 1976 they accounted for only 18% of all trainees and only 40% of the postdoctorals. In 1977 it is estimated that this decline continued.

The decline is not limited to individuals in training. In 1966 over 1,000 new principal investigators received NIH awards. Of this total, 471 were M.D.'s and represented 44% of the total. In 1975 the total number of new principal investigators was a little less than 1,400, but only 310 of them were M.D.'s, approximately 23% of the total.

These changes represent the outcome of numerous interacting causes, among which the following appear to be most important:

- The medical curriculum no longer includes intensive laboratory courses;
- the pace of scientific research is rapid, making the combination of research experience with clinical training a difficult one;
- the uninterrupted three-year period of clinical experience characteristic of resident training constitutes a serious interruption to development of research capability;
- research training stipends are lower than most resident salaries;
- the payback requirement is a serious deterrent to the individual who has not yet had his initial research experience;
- support for research training has been unstable for the past several years;
- the combination of research and patient care roles has become increasingly difficult for the individual to sustain.

M.D.'s in NIH Research Training Programs
1970-1977

Year 1/	No. of M.D.'s 2/	% of Total Trainees	% of Total Postdoctorals
1970	4,772	27	66
1971	4,631	26	61
1972	4,466	27	60
1973	3,612	29	66
1974	3,522	25	56
1975	2,790	22	48
1976 3/	1,915	18	40
1977 (est.)	1,700	16	33

Ratio: 1977/1970 = .36

1/ Funded in FY shown. Majority in training the following year.

2/ Includes all health professional (e.g. D.D.S., D.V.M.).

3/ Not including the Transition Quarter.

Source: IMPAC

IV.H. Should individual NRSA's continue to be required to be approved by the National Advisory board or council of the Institute which supports it?

No. Individual NRSA's are adequately reviewed, first at the institutional level, then by initial review groups at the NIH and then by NIH staff. Further review by council increases the delay between time of application and funding without adding corresponding value.

IV.I. Should health services research training, supported by the National Center for Health Services Research, be funded through the NRSA authority just as biomedical, behavioral and nurse research training is? Should all other research training programs of the Department be funded under the NRSA authority?

Health services research training and other research training programs of the Department are adequately controlled and operated without use of NRSA authority, and we see no particular benefits to be gained by putting them under NRSA authority.

It is difficult to administer the present authorization because of the split between NIH, ADAMHA, and HRA (for nurse research training). If additional organizations are entitled to the same authorizations, with the same internal requirements for individual fellowships, the possibilities of inadvertent error increase substantially.

If other organizations are added, it would be important to specify authorizations for each separately in order to minimize the possibility of such errors.

IV.J. Can section 473 of the PHSA be interpreted to authorize the Secretary to arrange for research training reports on specific matters in addition to the more comprehensive report of NAS which is being prepared annually under that section? If not, should section 473 be amended to specifically authorize the Secretary to arrange for reports by the National Academy of Sciences or other entity on specific research training matters periodically, in addition to the more comprehensive report presently required under that section?

The Secretary and other PHS officials have authority to arrange for research training reports that is not dependent on section 473 of the PHS Act. A contract with the NAS to study career patterns of bioscientists was completed two years ago, and further studies can be mounted as needed.

Information requested by Congressman Rogers, Chairman, Subcommittee on Health and the Environment of the Committee on Interstate and Foreign Commerce

IMPACT

When the Division of Nursing was included in the NRSA Research Training Program, authorized by Section 472 of the Public Health Service Act in FY 1977, it picked up the momentum of the previously existing Special Nurse Research Fellowship Program. This had been a highly active program which contributed in a major way to the nation's pool of nurse researchers, and the presently active NRSA fellowship program can be expected to have a dramatic impact on the pool of nurse research personnel in the future. The program is the major source of research training funds for nurse researchers, of which there are presently 1,800 in the nation. The Health Resources Administration does not support other types of research training. It is estimated that there are 50 to 100 new nurse doctorates annually. Since up to 40 NRSA fellows are in terminal phases of their doctoral education, it is estimated that the program can contribute a third to one-half of the annual number of nurse doctorates.

Relevant to the question of the program's impact on manpower needs and supply is a recently approved research project submitted by a national nursing professional association entitled "Nurse Doctorates: A National Information System/Model." Since one of the major purposes of this proposal is to develop a computerized information system as a basis for program decisions, manpower projections, simulation studies, and improved talent utilization, the project can be expected to generate much needed data in the future. The Division of Nursing considers this to be a project of high programmatic relevance.

APPLICATIONS REVIEWED AND AWARDS MADE

To date, over 3,400 requests for information have been responded to by the Division of Nursing, and 227 National Research Service Awards fellowship applications have been reviewed since the inception of the program at the start of FY 1977. Announcement has been made of the Division's new institutional award program to support research training in such areas as parenting, aging, and aspects of stress, pain, and chronic illness. To date, 120 individual fellowships have been awarded by the Division of Nursing under the NRSA program, as well as 3 institutional awards which will support an additional 7 trainees. (See tables 1 and 2.) Midway through the 1978 fiscal year, 84 individual fellowship applications have been reviewed, and another 51 are pending peer review.

BUDGETARY DATA

In FY 1977, an appropriation of $1,000,000 was provided to support 91 new NRSA fellowships and 3 NRSA institutional grants. In addition, 3 continuation awards were made to fellows under the old special nurse research fellowship program.

Congressman Rogers

An appropriation of $1,000,000 was again provided for the research training program in FY 1978. Thus far, 29 new NRSA fellowships and 25 continuation fellowships have been awarded.

THE NURSING RESEARCH AND EDUCATION ADVISORY COMMITTEE (NREAC)

The NREAC, which is the chartered peer review study group, charged with the scientific review of research project grant and NRSA research fellowship applications, is in the process of being terminated in response to the President's directive to reduce the number of advisory bodies.

The NREAC was chartered to consist of 14 experts "in the fields of nursing, the biological and behavioral sciences, and other specialized areas of health-related research which come within the jurisdiction of this Committee, such as administration and education." Specifically, the Committee is composed of 9 nurse scientists with expertise in anthropology, sociology, physiology, nursing education, public health, primary nursing, and field research, and 5 other scientists with expertise in medicine, statistics, psychometrics, psychology, and manpower research.

The function of the NREAC is to advise the Secretary through the Director, Division of Nursing, Bureau of Health Manpower, on all matters relating to Nursing Research and Research Training, including the scientific and technical or educational merit of research project grant proposals, and the qualifications and experience of NRSA fellowship applicants.

In FY 1977, the NREAC reviewed 89 research project grant applications, 143 NRSA individual fellowship applications, and 4 institutional fellowship applications, at a total cost of $21,787,572.

We are aware of the importance of peer review and the Subcommittee on Health and the Environment can be assured that some mechanism will be provided within HRA to ensure that nursing research and research training grant applications are reviewed by a group with the requisite nursing and related scientific expertise, prior to review by the National Advisory Council on Nurse Training.

We propose to develop a review group of nurse scientists that will include multidisciplinary competencies. It is important that there be one peer review group with primary responsibility for these programs of nursing research and nursing research training administered by the Division of Nursing.

TABLE 1

Fields of Study of Approved Fellowship Applications in FY 1977 and FY 1978 (through January 1978 Council)

Biomedical Sciences	Number Enrolled
Anatomy	1
Physiology	5*
Epidemiology	3
Behavioral Sciences	
Anthropology	10
Behavioral Sciences	1
Communication Sciences	3
Educational Psychology	12
Psychology	5
Sociology	10
Clinical Sciences	
Nursing	32*
Health Services Research	
Health Services Administration	2
Health Services	2
Other	
Education	24
Family Studies	2
Health Behavior	1*
Hygiene and Public Health	2
Organization and Policy Studies	2
Public Administration	1
Social and Preventive Medicine	1
Arts and Science	1

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* Includes 1 postdoctoral.

Source: Division of Nursing
Nursing Research Branch
Research Training Section, Unpublished Data
April 6, 1978

TABLE 2

Disciplines of Active Fellows Showing Numbers and Proportions of Applicants Enrolled in the Disciplines

Disciplines*	No. Enrolled	Proportion
Behavioral Sciences	41	34%
Clinical Sciences	32	27
Other:		
Education	24	20
Family Studies, Health Behavior, Hygiene, Policy, Preventive Medicine, Arts and Science	9	8
Biomedical Sciences	9	8
Health Services Research	4	3
Total	119	100%

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*As designated by the National Academy of Science in its 1977 report.

NATIONAL INSTITUTES OF HEALTH

Question V. A.

At the National Institutes of Health, nutrition-related research and other activities are coordinated through the Nutrition Coordinating Committee (NCC).

The NCC carries out its authorities directly under and is advisory to the Director, NIH. The members of the NCC consist of representatives from the 11 Institutes and two divisions, all of which support research in nutrition. The following are represented:

Division of Research Resources
Division of Research Services
National Cancer Institute
National Eye Institute
National Heart, Lung, and Blood Institute
National Institute on Aging
National Institute of Allergy and Infectious Diseases
National Institute of Arthritis, Metabolism, and Digestive Diseases
National Institute of Child Health and Human Development
National Institute of Dental Research
National Institute of Environmental Health Sciences
National Institute of General Medical Sciences
National Institute of Neurological and Communicative Disorders and Stroke

NCC liaison members consist of the following NIH representatives:

Clinical Center

Division of Computer Research and Technology

Division of Legislative Analysis, Office of the Director

Division of Research Grants

Fogarty International Center

National Library of Medicine

Office of Communications, Office of the Director

The following agencies outside the NIH have liaison members on the NCC:

National Institute on Alcohol Abuse and Alcoholism

National Institute of Mental Health

National Center for Health Statistics

Center for Disease Control

In addition to the above members, liaison is maintained with the Office of the Assistant Secretary for Health and with the Office of Science and Technology Policy.

Since DHEW established a Nutrition Coordinating Committee at the Department level last month, the chairman of the NIH Nutrition Coordinating Committee is a member of the Department's Committee. Thus coordination is assured within the National Institutes of Health, the Department of Health, Education and Welfare, and with the Office of Science and Technology Policy.

Activities of the NIH/NCC

The NIH Nutrition Coordinating Committee is involved in the following major activities:

- Reviews and comments on the plans, execution, and results of pertinent B/I/D research efforts relating to nutrition in order to develop an annual Nutrition Program of Biomedical Research at NIH.
- Processes and responds to incoming requests for nutrition information from the DHEW and other federal agencies, the executive branch of the government, the Congress, and outside institutions.
- Maintains up-to-date information on funding and on intramural and extramural research and training activities in nutrition.
- Develops and monitors means for improving coordination of these activities.

Functions of the NIH/NCC

Within the scope of the major activities described above, the NCC has several specific functions.

The NCC has prepared two particularly important items: a definition of nutrition research at the NIH, and a policy statement for research and training in nutrition at NIH.

An information exchange mechanism has been established by the Committee, whereby each B/I/D representative presents to the membership any new plans, activities, conferences, and workshops that are nutrition related. Future workshops and conferences are discussed to ensure full participation of all relevant Institutes; when many Institutes are involved, the NCC may sponsor or co-sponsor such workshops or conferences. Through the information exchange mechanism, the NCC is able to identify areas of collaboration for further research. The NCC informs the NIH nutrition community of all meetings, both within and outside NIH, that are concerned with nutrition. The Committee also reviews and comments on nutrition-related reports generated by the NIH and by other federal and nonfederal agencies.

The NCC has also developed mechanisms for receiving, reviewing, and distributing information on proposed legislation affecting nutrition policy. The Committee develops guidelines for use in the development of proposed legislation.

The NCC acts as a focal point for the dissemination of information for the purpose of public education in nutrition, health, and disease. The Committee also assists in coordinating B/I/D efforts in education.

An additional important function of the NCC is the development of an improved data retrieval system for research and training in nutrition. This system will involve both intramural and extramural NIH projects.

Recently the NCC has been in the process of developing joint program announcements in areas of common interest to the Institutes. These will eventually be developed as RFAs and RFPs.

V.B. How are testing programs for toxicity, carcinogenicity, mutagenicity, teratogenicity and other harmful effects of substances coordinated within the National Institutes of Health, within the Department, and with other public agencies?

As indicated in the answer to a previous question, the Department is currently reviewing the entire range of its toxicology testing programs to determine the most appropriate way to organize for the conduct of these activities. Clearly, whatever arrangement is selected, one of the Department's goals is to strengthen the coordination of these programs. Currently there are a variety of formal coordinating mechanisms in place. A start has been made, under auspices of the Council on Environmental Quality, the Interagency Regulatory Liaison Group, NCI's National Clearinghouse on Environmental Carcinogens, and HEW's Committee to Coordinate Toxicology and Related Programs, to improve coordination of chemical testing programs. The Coordination takes the form of consultations within these groups, as well as among staffs of the several concerned agencies, at several stages ranging from program planning, through chemical selection, and to reporting test results. Steps are being taken now to improve coordination, however, since at present the mandates of the agencies involved are relatively narrow. For example, NCI conducts tests to identify carcinogens; the National Institute of Environmental Health Sciences develops tests for mutagenesis and other toxic effects; FDA's National Center for Toxicological Research tests food additives and drugs and develops new tests systems; EPA and OSHA and other regulatory agencies conduct broad scale tests for a variety of regulatory purposes. HEW is in the process now of thoroughly examining the contents of these programs with an eye to consolidating and improving interactions among them. We will keep the Committee informed of our progress.

V.C. What are the Department's views respecting a statutory requirement that the Secretary (possibly) through NIEHS) conduct or contract for testing or other evaluation of the toxicity, carcinogenicity, teratogenicity, mutagenicity or other harmful effects of substances, upon the request of the head of any other appropriate entity of the Executive Branch of the U.S. Government, on a reimbursable basis for the full cost of conducting or contracting for such testing or evaluation?

As indicated in the answer to a similar question directed to NCI, the Department is currently reviewing its several activities in chemical toxicology testing and considering options for organizational consolidation or coordination. It has not yet been determined whether the resulting changes will accommodate a statutory role in chemical toxicology testing like that envisioned in the question.

Since the Department's capacity to conduct testing will be limited, even with a new arrangement for testing of chemicals, an absolute requirement to respond to all requests would be undesirable.

V.D. Should the law be amended to require that all testing of substances for toxicity, mutagenicity, carcinogenicity, etc., which is financed by Federal funds, conform to such protocols as the Secretary shall establish by regulation, except such testing which the Secretary may exempt for certain research and other purposes?

In general, we believe that the Government should establish standards for test protocols to be followed, except in those instances where research needs dictate a specific protocol. Dictating the protocol itself may result in satisfying the requirements of the protocol, but may fail to produce the data necessary to demonstrate safety or hazard. For this reason statutory provision would be undesirable.

The responsibility for the establishment of standards for testing in certain cases is currently assigned to the Administrator of EPA by the Toxic Substances Control Act.

V.E. Do you think that a national data bank should be established which would include an individual's medical history, demographic and occupational data and death certificates for deceased individuals in order to facilitate epidemiological studies? If so, should this be housed in and administered by NIH? The National Center for Health Statistics? Elsewhere? Would a feasibility study be desirable as a first step?

The National Cancer Institute has, for at least a decade, promoted the development of a data file which would permit immediate ascertainment of the fact, date and place of an individual's death. Such a file would permit implementation of effective epidemiologic studies designed to ascertain the fact of excess deaths among specific occupational or other high-risk groups.

In an effort to be responsive to Federal constraints regarding development of additional data files (and referencing existing data files) which might have the potential for invasion of personal privacy, the National Cancer Institute has taken the position that any such data file need not include individual medical histories, occupational data or cause of death. Such information can be ascertained when needed by securing a copy of the individual's death certificate filed in the locale of the individual's death.

Plans are now underway to establish a National Death Index, to be administered by the National Center for Health Statistics. An Interagency Workgroup, comprised of representatives of NIH, NCHS, and others, has been meeting to work out the details for such an endeavor. The planned operational deadline for the Index is January 1, 1979, and the system should be ready to receive requests by January 1981. The Index will provide information on deaths in the country to bona fide epidemiologists, or other researchers, both within the Federal Government and academia. Prior to the Index, collection of data on death was difficult, time-consuming, and costly, unless the State where each death occurred was known.

When operational, the Index will contain certain identifiers to enable the researcher to locate death certificates. Information in the Index will include: name, Social Security number, date of death, death certificate number, age at death, place of death, date and place of birth, sex, parents' names, descendant's maiden name, marital status, and place of residence at time of death and locale where death certificate is filed.

Mr. **Maguire**. Does anyone else have any comments before we break up this panel?

[No response.)

Mr. **Maguire**. Thank you very much.

Dr. **Fredrickson**. Thank you.

Mr. **Maguire**. The next panel is composed of Dr. Irving J. Selikoff, M.D., director of the Environmental Sciences Laboratory, Mount Sinai School of Medicine, and Dr. Joseph H. Highland, chairman of the toxic chemicals program, Environmental Defense Fund.

Gentlemen which one of you would like to go first? Dr. Selikoff?

SATEMENTS OF IRVING J. SELIKOFF, M.D., DIRECTOR, ENVIRONMENTAL SCIENCES LABORATORY, MOUNT SINAI SCHOOL OF MEDICINE, CITY UNIVERSITY OF NEW YORK, AND JOSEPH H. HIGHLAND, PH. D., CHAIRMAN, TOXIC CHEMICALS PROGRAM, ENVIRONMENTAL DEFENSE FUND

Dr. **Selikoff**. Thank you very much, Mr. Maguire.

I appreciate the opportunity of being here with you. I have just come from another meeting, of the International Chemical Workers Union, and they have asked me—Mr. Frank Martino their president—to extend to you their best wishes for a very fruitful consideration of what they conceive as their problem, as part of the overall problem of cancer. It is because of this very recent intimacy that I would like to spend a few moments stressing my evaluation of two very important questions that might be considered by your committee in its analysis of the renewal of the National Cancer Act.

I refer to the importance of prevention, and the potential for such renewal and orientation, shall I say reorientation, on the part of the National Cancer Institute in this regard.

In the past 10 to 15 years, considerable progress has been made, in no small part due to the activities of our Congress, for example, in establishing the National Institute of Environmental Health Sciences 10 years ago, and in the markedly increased support for cancer research in our country. As a result, we have begun to identify causes of cancer in our population. There is hardly a year now that goes by that this list is not being considerably lengthened, and we have reason therefore to hope that we will, within our lifetimes, identify those things that are causing cancer among us, and with that, have the opportunity to prevent such disease.

I would urge you then to continue and to emphasize in the activities of the National Cancer Institute the work that is now necessary to further identify the causes of human cancer, most of them being clearly in the environment. Even those for which causes are not known—breast cancer, colon cancer, stomach cancer, prostate cancer—there is enough information to indicate that these causes, too, will be found to be environmental.

We have the tools now to be able to do this. We know how to examine the experience of human populations. Our bitter experience with cigarette smoking has taught us that. Our bitter experience with asbestos has taught us that, and our experience with bencidine, betunaphtalamine, arsenic, nickel, cadmium, and so forth have shown us how to find the links between exposure to these agents and human cancer.

Second, we have begun to learn how to evaluate and analyze animal experiences to do the same thing.

With these tools in hand, it would be, I suggest, an incomplete acceptance of our responsibility if we do not use them to now find the remaining causes for human cancer: why one woman will develop breast cancer and not another; why one man will develop colon cancer and not another.

The second aspect of prevention that is before us and, again, feasible reflects a different opportunity. The first will hopefully help us avoid exposure in the future. The second will assist us in making amends for our ignorance and inattention of the past.

I refer to the fact that as we have identified causes of cancer, whether it is asbestos, or chromium, or bischloromethyl ether, or chromates, or whatever, we have simultaneously identified large groups of people who have been exposed to them. These groups then are at high risk of developing cancer in the future. The groups of people who smoke three packs per day, the groups of people who work in shipyards and were exposed to asbestos, the groups of people who used benzidine and betanaphthylamine in the manufacture of aniline dyes, the groups of people who, when making plastics, were exposed to vinyl chloride, acrylanitril, and vinylidine chloride, the people who used solvents that contained benzine, these groups, then, will have important increased risk of cancer in the future.

There are two things we can do. Either we can stand by and keep score, sort of biological bookkeepers, in a sense, or we can try to intervene. We know who these people are. The potential for surveillance, the potential for early diagnosis, the potential for early treatment is now afforded us. Indeed, there is even the potential, on a research basis, for learning how to make preclinical diagnosis and ultimately to look to preclinical treatment.

I would urge that the National Cancer Institute be asked to review its programs that will be devoted to such prevention, to learn how to maintain and establish surveillance of high-risk groups, how, in other words, to save lives among those who have already been exposed in the past.

As a supplement to both of these areas of considerable potential, I would urge, too, that the National Cancer Institute review how it might make its considerable resources, scientific, intellectual, administrative, financial, available to those in the community—trade unions, industry, other groups—who are initiating examination of suspect problems, problems that they are beginning to look at. Very often there is now nowhere to turn.

When a group of workers, when an industry or other groups in the community meet these potential problems, they do not know how and where to have an appropriate evaluation made. I need only remind you, Mr. Maguire, of the unhappy situation in Michigan where, from 1974 to 1976, there was nowhere for the dairy farmers to turn to see whether this problem might include a cancer risk in the future for them, nor in fact do the 9 million people in Michigan have such opportunity.

I would urge, therefore, that the resources of the National Cancer Institute be made more intimately and openly available to the many groups in our country who are more and more approaching these problems. Thank you very much for the opportunity of reviewing these perspectives with you.

Mr. MAGUIRE. Thank you.

Dr. Highland?

STATEMENT OF JOSEPH H. HIGHLAND, PH. D.

Dr. HIGHLAND. Yes, thank you, Mr. Maguire.

Members of the committee, I am Dr. Joseph Highland, chairman of the toxic chemical program of the Environmental Defense Fund. EDF is a nonprofit, public interest group with over 45,000 members that has long advocated elimination of unnecessary human exposure to toxic chemicals. Before joining the EDF staff, I was a staff fellow at the National Cancer Institute. Currently, I serve as one of two public interest representatives to the NCI, as a member of the National Clearinghouse on Chemical Carcinogenesis. It is a pleasure to have this opportunity to discuss briefly the issue of emphasis that should be taken to solve the cancer problem.

I will limit my remarks, because you have already discussed today in previous testimony the knowledge we have in terms of our latest understanding that 80 to 90 percent of all cancers are environmentally caused. You also realize the extreme importance of this disease and the near epidemic proportions it has already reached. Each day, an estimated 1,000 men, women, and children will die of cancer. It has been our increased understanding of the environmental nature of this disease, coupled with our knowledge that cure rates for cancer, except in rare cases, have increased only slightly over the past decade, that has led us to heavily stress the need for cancer prevention.

Once causative agents of diseases are identified, it is only a logical step to seek their elimination. Prevention of disease rather than cure has historically always been our approach.

In some cases, we have acted wisely, unfortunately, after tragedy. Occupational exposure to vinyl chloride has been greatly reduced, thus reducing human risk, so, too, has exposure to several other recognized occupational carcinogens, such as asbestos and bischloroethyel ether, but our general efforts to limit or eliminate human involuntary exposure to chemical carcinogens in our environment have been inadequate and painfully slow in coming.

Effective action under section 112 of the Clean Air Act, section 307(a) of the Federal Water Pollution Control Act, or the general provision of the Safe Drinking Water Act have been extremely limited. The Environmental Protection Agency as the responsible Federal regulatory agency has moved only when confronted with legal action or extreme public pressure. Likewise, the Food and Drug Administration has used the Delaney amendment less than a handful of times to protect the public from the addition of known carcinogens into our food supply.

The Consumer Products Safety Commission fares no better, and the risk of chronic hazards such as cancer from the use of a variety of consumer products remains unregulated. In some cases, the necessary and proper regulatory authority has not even been granted by Congress. An example is in the area of cosmetic safety. Today, cosmetics continue to enter the marketplace without any requirement that they be premarket tested for safety. The American people are thus exposed to thousands of cosmetic ingredients about which we have little if any health effects information.

Why has regulatory action been so slow? Often, regulation has hinged upon the availability of scientific data. Many times the data necessary for regulation has resulted from experiments performed under the bioassay program at the NCI, but years of delay in finishing experiments have caused intolerable delays in the publication of vital scientific findings. These delays are indicative of a failure to emphasize cancer prevention at the NCI, and these delays have been costly.

For example, the CPSC did not act to ban use of the flame retardant "Tris" until the results of the NCI bioassay on "Tris" were made publicly available. Likewise, FDA action to warn consumers of the risks posed by the use of certain hair dye products was linked to the publication of the NCI bioassay report on 2,4-diaminoanisole sulfate, and EPA's effort to curtail the discharge of two hazardous pesticides, endrin and toxaphene, into the Nation's waterways would have been vastly altered if the bioassay data on these two chemicals had been available at the time of the regulatory action.

I cannot stress enough how vitally important it is that a clear and definitive emphasis on cancer prevention rather than cancer cure become the primary objective of the NCI. In a time of limited resources, more emphasis must be placed on truly preventive action. Better coordination is clearly needed, and even greater efforts in the area of human epidemiological studies must be undertaken.

This is not to suggest that efforts in basic research are useless. To the contrary, they will be vitally important to our ultimate understanding of the nature of the carcinogenic process, but the past emphasis on cancer cure rather than the prevention has meant that much work vitally needed for effective prevention has remained undone. Not enough money has been appropriated for long-term bioassay testing of potential carcinogens. Currently, only 50 to 60 new chemicals a year can be tested because of limited resources.

Mr. FLORIO. Doctor, on that one point, are you familiar with OSHA's relatively new initiative of attempting to classify these? Do you see that as a way of addressing this problem, shortage of resources?

Dr. HIGHLAND. I see it as an attempt by a regulatory agency to address the problem of regulation, but the basis of regulation that OSHA is proposing is one based upon the type of data they have to go with, and what I am trying to say here is that in many cases we have failed to have proper regulation because the data has not been generated, so when OSHA says it has one animal long-term bioassay report and one short-term test or two animal bioassays, it will take the following regulatory step, part of the question is, where will it get that data, and are some of those tests now being performed by NCI, or have they been performed in the past, and have we seen a lack of rapidity in getting out information necessary for regulation? That is the emphasis of the point here.

Efforts to develop short-term screening tests such as the Ames mutagenicity assay have been underemphasized and consequently underfunded. The use of short-term mutagenicity data will be critical to the policy. To date, there has been a small effort at the NCI to start to use that screening test, to start to validate it better, but that effort has been underfunded. It is sort of a low priority, and it needs a lot more priority and a lot more emphasis. This condition should not be allowed to continue.

It is critically important that you realize that the decisions you make today are critical to the lives our children will lead tomorrow. To date, we have acted too slowly, and without sufficient concern. As a result, human exposure to hazardous chemicals has greatly increased over the last decade, and is now occurring at an earlier age and to a greater extent than ever before.

Children in utero are being exposed to carcinogenic pesticides and industrial chemicals. Many of these same chemicals contaminate human breast milk. The levels of these chemical contaminants is so high that if cow's milk were as contaminated as the average woman's breast milk in this country, it could not be sold in interstate commerce.

We are forced in many cases to conclude that the risks of breastfeeding may now outweigh the benefits. As an example, in the first year of life the average nursing infant whose mother's milk is contaminated with PCB's, the chemical you asked about before, that infant will ingest what you or I would ingest in a decade of life, but still the Environmental Protection Agency has not gone forth as required to properly take care of that issue, and that same child will be ingesting PCB's at a dose approximately 100 times that of an adult, on a weight basis.

The statement that cancer is an environmentally caused disease is often misrepresented to mean that cancer incidence reflects exposure of manmade chemicals only. This is clearly not the case. Factors such as sunlight, natural radiation, diet, and smoking are clearly included, but it is likewise important to remember the conclusions of a Presidential Science Advisory Committee which in 1973 concluded that:

> Cancer incitemenst by so far unrecognized chemicals combine to form a threat to health that may well be of at least the same general size as the three major threats just described [i.e., cigarette smoking, alcohol abuse, and choice of dietary composition]. These chemicals may be natural or synthetic.

Moreover, I would suggest to you that the full impact of human exposure to chemical carcinogens has not yet been felt, and may not be felt for another 5 to 15 years, and this, I think, goes particularly to Mr. Maguire's concern of the synthetic chemicals being released into our environment. To illustrate this point, I ask you to recall the demonstrative relationship between smoking and lung cancer. As cigarette consumption rose, so did lung cancer rates, but only after a characteristic "lag time" or "latent period" of approximately 30 years. The lung cancer incidence we see today clearly reflects the smoking habits of 30 years ago.

If one now looks at the production of synthetic chemicals such as plastics, pesticides, and synthetic rubber, one notes a striking increase in production starting in the 1950's, and I would direct your attention to a graph I have included on page 6 of the written testimony I have submitted for the record, in which is plotted production levels as a function of time [see p. 170].

Although production clearly does not equal human exposure, it certainly is indicative of exposure, especially given our almost complete failure to control the discharge and use of many of these hazardous chemicals. Consequently, if a pattern similar to that of smoking occurs in that a 30-year lag time exists between exposure to these chemicals and the manifestation of disease, the effects of general exposure may not be seen until the mideighties.

Clearly, the time for action is long overdue. Through our current inaction, we have jeopardized our futures, but appropriate action today can turn the tide and bring us effectively onto the much-needed path toward cancer prevention.

Before I finish, I would like to just state a general support for the items which are listed in H.R. 10190, and specifically address two of the issues raised by Mr. Maguire. One is the altering of the composition of the National Cancer Advisory Board, and the other item is better coordination with other agencies between NCI and these other agencies, both after data is generated and before, when deciding on what chemicals should be tested and how. Let me amplify on those thoughts.

I would have to strike a note of difference with Dr. Fredrickson's answer to Mr. Florio's question on coordination, at least with respect to the issue of coordination after data generation. My experience is limited to the activities that I have taken part in in terms of the clearinghouse, but one clear example where an agency asked for help and did not get it was in the issue of Tris. The Consumer Products Safety Commission delayed action for approximately 4 to 8 weeks, seeking from the clearinghouse some calculation of estimated human risk. The clearinghouse refused to do that. The only way they got that information was when EDF asked Dr. Marvin Schneiderman of the National Cancer Institute to make a public presentation to the Commission in which he presented the models and a series of calculations which could be done.

At that time, the Commission agreed it would like Dr. Schneiderman to do those calculations, and they were performed.

Mr. Florio. Would you speculate on why the Institute appears to be reluctant to provide the types of information we are talking about?

Dr. Highland. I can only limit it to my experience. I do not have good knowledge of the many committees Dr. Fredrickson spoke of, but only the clearinghouse. The clearinghouse has met probably now for close to 2 years and has gone about its task in a tortoise-like fashion, in the sense of being slow to deal with the issues of risk assessment, those kinds of tough questions.

Part of it may relate to the structure of the clearinghouse and the fact that it meets so infrequently, and that part of the time is spent just getting going again, and the day ends. I cannot tell you exactly why, although there are differences clearly in terms of the acceptability of different models of risk extrapolation.

The Consumer Products Safety Commission was asking for some idea, some feeling for the order of magnitude of risk. It was not asking for a definitive statement, and at that point a decision was made by the chairman of the subcommittee of the clearinghouse simply to say that they would be unable to give the data. I cannot give you the reason for it. The appropriate people to ask would be Bud Brown, the chairman of that particular subcommittee at the time, but it is indicative of a failure once data is generated for at least one body of the cancer institute to respond to a regulatory agency's request for help. There is an equally important point that goes with this, and I would like to mention that before closing.

That is, in terms of the types of experiments to be done, to recognize the hazards of the future, what chemicals to be looked at and how to look at them. We continue to put on tests in the bioassay program, a series of chemicals, without regard or knowledge of how the information generated from those tests will be used in a regulatory sense. For example, if you want to do proper risk extrapolation, you may need several data points, which as the tests are currently designed, will simply not be generated, so you can run a 3-year, 4-year test costing $250,000, and fall short of the kind of data that a particular agency wants for regulation.

There are committees to look in terms of the clearinghouse at this problem. They are supposed to have been looking at it for the past year and a half without much progress, but it is essential, as much as the help after data is generated, to make sure the data we are generating for the future is of the appropriate nature for proper regulation.

Thank you very much. I would be glad to answer any questions you might have.

Mr. MAGUIRE. Thank you. Mr. Florio?

[The graph Dr. Highland referred to follows:]

FIGURE 1*

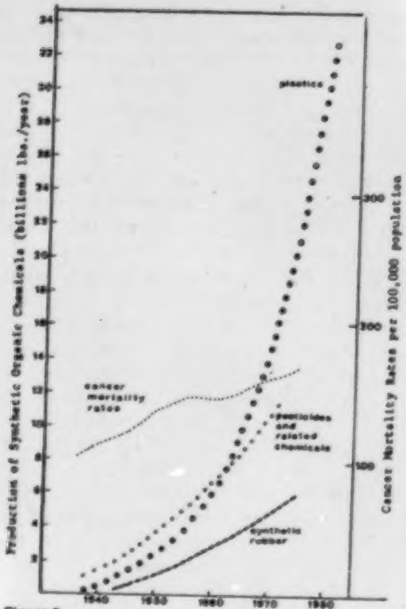


Figure 2
Cancer mortality rates and chemical production as a function of time.

*Harris, R.H., T. Page and N.A. Reiches, "Carcinogenic Hazards of Organic Chemicals in Drinking Water," in Origins of Human Cancer, 1977, Cold Spring Harbor Laboratory.

Mr. **Florio.** Unfortunately, I have to leave now. I have great admiration, Doctor, for your contributions in the past, particularly with regard to the asbestos question. If you do not mind, I am going to submit a couple of questions to you, and I would appreciate your response, particularly on the asbestos question. Likewise, I apologize for interrupting, but I asked most of my questions as we were going through, because I knew I would have to leave.

Mr. **Maguire.** Thank you.

Mr. **Florio.** Thank you.

Mr. **Maguire.** Thank you, Dr. Highland, for your favorable comment about H.R. 10190.

I wonder, gentlemen, if we could talk about some more specific suggestions that I and others have made about augmenting NCI's responsibilities. I have suggested, for example, that given the tortoise-like nature of the clearinghouse process and the "coordination" process which we have had under various guises in recent months and years, that we should identify a lead agency.

I have proposed that it ought to be NCI to promote the systematic pursuit of the identification of carcinogenic substances. That would include, of course, proper tests, processes, and some establishment of priorities, but to provide the data base for the policymakers in whatever agency, I have suggested further that NCI as the lead agency ought to be required at the request of any agency to either test or make sure that proper tests are done with respect to any substance that is regarded by an agency as an actual or potential hazard.

I have suggested further that NCI ought to report annually on the substances which are suspected with respect to where we stand in each case, on testing on regulatory action, on exposure of high risk populations, and so on.

Do those sound to you like reasonable suggestions for legislation, either or both of you?

Dr. **Selikoff.** Yes. I think your proposals are very modest, very much to the point, and very much in tune with the developing and current leadership at the National Cancer Institute, and I think they will provide very useful information for the Congress and for our people in the future.

Mr. **Maguire.** Dr. Highland?

Dr. **Highland.** Yes; I would like to respond to those points. As far as the coordination role that NCI plays, I think it is a very good idea. I understand Dr. Fredrickson's expressed concern that we not limit our interest in a chemical's toxic properties to cancer. If it has other properties, we should know at the same time and coordinate our testing. I think that is clear to everyone. If that is a problem in terms of putting it under the National Cancer Institute, I am not sure why, in the following sense.

The work done by NCI right now is on contract and clearly, if it is of concern, whether there are other tests running coordination, those could be handled at the same time. I strongly concur with your feelings that there is a need now to pick somebody and get some responsibility and get the job done. NCI seems like a logical place, because our knowledge about cancer mechanistically and about the kinds of factors which affect human cancer rates is probably greater than, for instance, our knowledge in terratogenicity, and if we wish to develop more tests and understandings, that everyone would support that concurrent with our understanding of the carcinogenic nature.

For the second point, test whatever is asked for by a regulatory agency, that would require clearly a great increase in the budget that the testing program has.

Mr. **Maguire.** The bill would provide that wherever another agency made the request, that agency would be responsible for the funding.

Dr. **Highland.** I think that is very appropriate. I know in one case in the clearinghouse the Department of Defense wanted something tested, and the decision was to ask the Department of Defense for the funds or simply advise them how to do the testing. The only problem I can see with that is that, for instance, the EPA recently requested that three trihalomethanes which appear in drinking water be tested for carcinogenicity. We have already had data on chloroform, which appears concurrently with these in drinking water. We had mutagenicity evidence on these chemicals, and I question the need to spend $1 million to test the others if regulatory action was appropriate based upon the knowledge we already had.

So, I think there is a need to be able to judge the appropriateness of the request, but certainly, if it appears to be the kind of request which will help in the regulation of these hazards, I would certainly support it.

As far as where we stand on questions of high risk groups, I think it is vitally important. We issue today reports from the National Cancer Institute which do not even have a thorough search in many cases of existing literature which would complement the findings or data from other regulatory agencies which could give a fuller picture to the question at hand about carcinogenicity of a particular chemical.

May I also, since I did not in the statement I made before—I mentioned I would like to support your suggestion for an expanded National Cancer Advisory Board. I think it is clearly needed, and I obviously would support the types of groups you would like to add to it.

Mr. **Maguire.** You don't think——

Dr. **Selikoff.** Mr. Maguire, may I interrupt and ask you how your bill would assist in the focusing by the NCI on high risk groups?

Mr. **Maguire.** Well, if you would just hold that for a second, I would like to come to that. It is my next question. On the point that Dr. Highland was raising, out of some 23 or so members of the board, my bill suggests we ought to have at least 6 who are especially trained in environmental or occupational exposures, carcinogenesis.

An alternative proposal is that we have three. I just wondered if you felt that six was a prolific amount.

Dr. **Highland.** I would suggest that six is clearly appropriate, and I would make what will probably sound like a self-serving suggestion. I suggest that specialists in environmental concerns include perhaps representation of public groups, not only highly trained specialists, so the six sounds appropriate. It may not, in terms of our views, even be sufficient to get the broad spectrum of representation we believe would be necessary.

Mr. **Maguire.** Dr. Selikoff, do you have any comments on the number of persons with special experience and expertise in environmental and occupational carcinogenesis that might usefully be required on the board?

Dr. **Selikoff.** Well, it depends on the people. Two might be enough, and six might not be enough. I think with six you have a chance of getting two good ones.

Mr. **Maguire.** Let's move to the populations at high risk and the screening proposal. Dr. Selikoff, my bill simply contains the following language, that there be programs, including programs to identify and screen populations having a high risk of developing cancer because of occupational or environmental exposure to known or expected carcinogens. We don't spell that out, and I was just about to ask you if you had some suggestions about how such a screening process might best work.

You emphasized that in your opening statements, and I suspect you have given it some thought.

Dr. SELIKOFF. Yes, it would take no great new body of science to identify many groups now at high risk of developing cancer in the future. We recently had another example added to those we have already had in the report of the University of Chicago's study concerning women who, from 1950 to 1952 were given diethylstilbesterol. There were some 668 such women, and they have now been traced with an appropriate control group to 1977.

Until now, we had been aware of the danger to their female offspring of developing cancer of the vagina. The new data from Illinois suggests that women—and there are some 2 million in our country who were so treated in the early fifties—that women who were so treated have approximately twice the risk of developing breast cancer. No new body of scientific data is needed to teach us how to keep such women under surveillance, to minimize the results of our previous ignorance of 25 years ago.

How to identify these people, however, will require some ingenuity and demonstration research. For example, the Navy at this moment is scratching its collective heads on how to notify men and women who were employed in our shipyards in World War II and subsequently under conditions in which there was considerable risk of asbestos exposure, and who therefore are at risk now and in the future, for the next 30 years or so, of developing cancer.

How do you notify these people that they should place themselves under surveillance? How do you teach doctors what to do about it? How do you save lives? How do you tell people who worked in shipyards they should not now be smoking cigarettes, so they could cut their lung cancer risk perhaps in half. We don't know how to do this. But this is certainly amenable to investigation, and among the lead tasks that you are assigning to NCI, I see no reason why this should not be added.

How do we identify, notify, and keep under surveillance these people who in the past have been exposed to these chemicals. There are 4.5 million Americans now alive who worked in our shipyards during and after World War II, including many, Mr. Maguire, in your district, Bergen County. In the New York Harbor area, the New York-New Jersey area, Hoboken, Bayonne, Staten Island, Brooklyn, et cetera. This is something that we can do and that we should do. If we do not, I do not think we will be taking the opportunity that is now afforded us.

The National Cancer Institute is taking a leading role in coordinating for the Department of HEW the development of approaches to the shipyard problem from here on in, and your bill will codify, stimulate, and assist them in similar acceptance of lead responsibility for the future in this extraordinarily important area, including, incidentally, the whole petrochemical industry in New Jersey.

We have just completed a study of maintenance workers at the American Cyanamide plant in Bound Brook. It was the report of this study that I was giving this morning to the International Chemical Workers Union. It was found that among the maintenance workers (and, as you know, in the petrochemical industry perhaps most workers are categorized as maintenance workers—they are not just chemical operators pushing buttons, but are plumbers, steamfitters, electricians, carpenters, welders, boilermakers, and so forth) approximatley half and X-ray evidence of asbestos disease, because of inappropriate use of that material in past decades. Here, then, is a major problem throughout our country, but also very much in your district.

Mr. Maguire. One of the criticisms that has been made of the National Cancer Institute's activities in the past is that the Institute has been an institute oriented too exclusively toward sophisticated scientific analyses, without much sense of the urgency of moving in a policy way to protect people's lives at any given moment in time, based on the best information we have available.

When you talk screening and you talk reaching many, many tens of thousands of persons in some way, you are talking not only about moving beyond research to policy, you are also talking about moving beyond policy to outreach, and execution of programs. Do you think that the National Cancer Institute is the appropriate place to lodge those kinds of responsibilities?

Dr. Selikoff. Some of them, yes; some of them, no. I do not think that the National Cancer Institute can appropriately accept the task of what you have correctly termed outreach. I think that is much more properly the task of OSHA, the task of perhaps other regulatory agencies, and perhaps agencies that we do not now have. We have not in this country been following people who are at high risk. Virtually none of the 20,000, 25,000 vinyl chloride polymerization workers whom we knew in 1974, in January 1974, to be at risk are now under observation. The very large majority are not, nor are the 1 million or so vinyl chloride—polyvinyl chloride production workers extruding, coating, calendering, the material and exposed to considerably lower levels of vinyl chloride. We are not keeping former benzidine-exposed workers under observation. We are not keeping former betanaphthylamine workers under observation. We have no agency at this time that has the task of doing it. I do not know whether it should even be a Government agency.

The unions now are looking to their responsibility in this regard. I do not know if they wll wait for the Congress or HEW or OSHA or the Department of Labor, to do this. Someone is going to do it. I don't know whether it should be HMO's. I don't know what the mechanism will be in our country and in our circumstances to do this, nor do I find that there are lessons coming from abroad.

Mr. Maguire. Would you say, though, that it would be sensible to assign NCI the task of assuring that this kind of effort is in fact in place?

Dr. Selikoff. I do not think that they could assure it. Their task should be a research task, to do the research that would tell us how to do this. In the division headed by Dr. Fink in the NCI, there is the authority now, and you could spell it out very clearly, and you can encourage it very vigorously, that the necessary demonstration projects be undertaken that would teach us how to keep peoploe at high risk under surveillance, to evaluate the value of such surveillance. If the NCI does not do it, if our Congress does not do it, we will have to do it some other way.

Mr. **Maguire.** Of course, we have health services programs of various sorts spread around the country now under HEW and presumably we ought to use existing frameworks for reaching people, or are you of the opinion that those frameworks are not adequate?

Dr. **Selikoff.** I would be delighted if we used these frameworks, and they worked. But I will ask you, Mr. Maguire, which comprehensive cancer center in its own area is now keeping under surveillance a single group at high risk of developing cancers in the future? We have, what,some 20, 22 such centers? We are spending hundreds of millions of dollars? Are we keeping people under surveil lance now? Are we doing what we can do to minimize the risk of death of cancer among these people? We have frameworks. If the framework can be utilized, fine. But if we cannot use the frameworks we have, we simply must have others.

Mr. **Maguire.** Dr. Highland?

Dr. **Highland.** I do not have a magic solution, but I would suggest to you that the question you are really asking gets to the heart of the matter of the responsibility of NCI in terms of not only studying people at high risk, but the general public education, the whole effort to reach the public and develop this understanding, and in that sense, NCI in the frameworks, we have failed. We still have people confused by what these exposures may mean to them in the future. We still have them confused as to what the data from the National Cancer Institute on any one chemical means. How significant are animal data and high dose testing?

There is certainly a role and responsibility to develop that public understanding and to go further to reach those people who have been exposed and who are at high risk, and there are frameworks, and they should be, in a sense, told that they have to work. Clearly, I agree with Dr. Seilikoff that if the frameworks do not work, something else must happen, but at this point I think there is no excuse or no justification to saying they will not work. I think that that has to be pushed.

Mr. **Maguire.** I pursued with Dr. Fredrickson this morning the question of coordination. He suggested that we ought to have better coordination, that we ought to have these clearinghouse procedures. He was not sure that NCI was the place to assign a lead responsibility. I found myself rather surprised at the testimony, frankly, because it has seemed to me that you can coordinate, coordinate, and coordinate and unless someone is responsible, nothing happens at all, other than people talking to each other, which is not enough, and therefore I found myself surprised at his response. It seemed to me that he was giving those of us who want to see a lead agency established very little encouragement.

I wonder, Dr. Highland, if perhaps you have a comment. I think you heard this testimony.

Dr. **Highland**. Yes. I think what you are hearing, and I do not attribute the following to Dr. Fredrickson, and I do not know his personal views at this point, but there is a feeling within the National Cancer Institute that if the whole bioassay program could be removed from NCI and set off in another institution where every other kind of test were done, that that might be desirable.

I think that you are seeing—basically, you have an academic institution. When I worked there, it was no different than working at other kinds of academic institutions. All of a sudden, you have the results of bioassays coming out which talk about flame retardants like Tris or hair dyes. This moves an institution which is basically a research generating kind of institution into a political forum, and it is an uncomfortable position, perhaps, and there are those within the agency who have said to me that if they could get away from that, they would like to get away from it.

What you are suggesting is a further immersion in that kind of activity, and you may be detecting a reluctance to have that. As I say, I cannot attribute that to Dr. Fredrickson, as I have not spoken to him, but I know from others I have spoken to in that bioassay program there is strong concern that it is an awkward position. They are not sure how to handle it. It is much easier to continue to develop tests, screening procedures, et cetera.

As far as coordination and clearinghouses, I think the clearinghouses are a good example of where you see a failure of that kind of coordination. Sure, there are members from different regulatory agencies as part of the clearinghouse, but what impact that clearinghouse has had on those regulatory agencies, or what impact they have had on the workings of the clearinghouse, I think, could be quantified as being infinitessimal, and that is the real problem. Someone has to have that responsibility, and someone has to make sure that things go in an aggressive, good sense, and that is simply not occurring.

I don't disagree with you. I understand, as I said Dr. Fredrickson's concern that we look broadly at chemicals as a much better use of our time and money, but I think you may be detecting a reluctance on the part of NCI to get involved in a deep way into that kind of role.

Mr. **Maguire**. Dr. Selikoff, have you any comment on this?

Dr. **Selikoff**. I think that what Dr. Highland says is correct in interpretation. I am not sure it is correct as policy.

Mr. **Maguire**. You are not sure which is correct as policy?

Dr. **Selikoff**. That there should be an acceptance of such reluctance to become "involved."

Mr. **Maguire**. Well, they are involved. If I might just comment, they are involved to the tune of nearly $850 million a year.

Dr. **Selikoff**. That is correct. I am interested, of course, in how the base pairs twirl on the DNA. But the real reason for the NCI is to decrease the amount of human cancer in our country. The information that we seek is sought for that particular purpose, and they are very much involved in a very important human problem.

They may want to select their spokesmen with thick skins to come before committees like yours of public forums. That is all right. But their information should become useful as we approach the problems of control of cancer.

Otherwise, well——

Mr. **Maguire.** I should think so, too, but I might point out the data I have available to me shows that during 1967 to 1973, only 41 percent of white male cancer victims survived more than 5 years. That is not much change from 1950 to 1959, when the rate was 39 percent, and this is apropos of the point that if you prevent someone from getting it in the first place, you are one heck of a lot better off than trying to deal with it after somebody gets it.

Dr. **Highland.** May I just make a comment on that?

Mr. **Maguire.** And there has been very little progress on the back end of that in the 20 years we have been working on it.

Dr. **Highland.** That is right, and as Dr. Upton said, there are limited cases of childhood leukemia where you see greater increases, and maybe Dr. Selikoff knows this, obviously, a lot better than I do, but if you look at our treatment of medical disease in this country—take polio as an example. We never approached polio by saying, let's find a cure for polio. In other words, let's have the victims get polio and then we will treat them and have them cured. We have always looked for preventive measures in disease control.

What you are running into here, I suggest to you, is the fact that a lot of what you want to prevent, those agents out there have political overtones to them. They are not clearly a nice virus that no one has an interest in, and that is the stumbling block to a lot of the progress that should be being made. It is not typical to dwell so heavily, I think, on a cure. Clearly, for those people who have been exposed, for those people who do have cancer, there is a need for treatment, but I think if we take the perspective approach, we have to be emphasizing more in the future prevention, be it through screening programs of people at high risk so we can do something about that if the disease is manifested, or more importantly in terms of what is going to happen 25 or 30 years from now. What steps are we taking now to avoid having to look at groups at high risk in the future?

Mr. **Maguire.** Again, going back to Dr. Fredrickson's statement, he introduces a paragraph by saying, "Cancer prevention is one of the most important goals of the National Cancer Program," and then he goes immediately to a discussion of clinical trials soon to be undertaken to test the value of a chemical relative of vitamin A that scientists believe may reverse the action of known cancer-causing substances, and then to a discussion of cell surface antigens which have been shown to prevent the growth of cancers in experimental animals.

Now, I suppose in a sense those are preventive strategies, and if something like that could be found to work, it would be marvelous indeed, but I wonder if either of you would care to comment on chemical relatives of vitamin A and cell surface antigens with respect to whether or not either or both of those seem to you to suggest that we may have the end of the tunnel in sight here with respect to dealing with cancer.

Dr. **Selikoff**. I have three comments with regard to that. The first is that if we don't know who to treat with retinoic acid, which is the chemical relative of vitamin A, it certainly will be another tool in our drawer we will never use.

Mr. **Maguire**. Even if it works?

Dr. **Selikoff**. Even if it works. Once again, unless we approach the serious problem of defining, treating, and keeping under surveillance people at high risk, it will be another piece of information which we will not use, and which, incidentally, I think the American public will be surprised about. They think and I think—in many areas I am a layman that research (at least publicly supported research) is done so that the results can be practically used.

Mr. **Maguire**. You hope it is.

Dr. **Selikoff**. We not only hope; we sort of anticipate that. That is what a reasonable man would do. So, I think not doing it would surprise many people. Secondly, we have known about retinoic acid now for a number of years. This is not a new discovery, and there is research under way, limping along in this regard. It is my hope that it will be useful, and I think certainly should be explored. With regard to the immunological approaches, which is another term for the cell surface antigens, I think that Dr. Fredrickson has reason on his side to at least hope for this.

Let me tell you of an experience I have had. Our patients with mesothelioma caused by asbestos have almost uniformly died within a year or so of diagnosis of their condition. It is a bad disease. We have very few cures, if any. We did one little study of 11 patients. Dr. Bikesi at our hospital, with mesothelioma, looked at the cell surface antigens in B-cell, T-cell, lymphocytes.

Ten of the 11 showed marked immunosuppression. Their immune systems were not working. All 10 were dead within a year. We had one man who for reasons I do not know had perfectly normal lymphocytes, normal immune status. He is now 6 years since diagnosis. I thought perhaps we had mixed up the slides, perhaps it was the wrong diagnosis. So, we did a thorocotomy with biopsy a second time. We were right, it was a mesothelioma. He is now 6 years post diagnosis. He has had no treatment. Somehow his status vis-a-vis his tumor is that he is allowed to continue to be alive. He still has his tumor.

There are some secrets that nature is trying to tell us in which the immune status may be important, and I would strongly urge that the NCI continue this area of research. Basic research is critically important, It must also be, I think, in everyone's opinion, closely tied with the pracitical problems we are also looking at, so that it can be utilized rapidly and well.

We may never discover some of these secrets. For example, we do not know how cigarette smoking causes lung cancer. We do not know which of the literally thousands of chemicals found in cigarette smoke might or might not be responsible for this. But we know that people who do not smoke cigarettes do not die as much of lung cancer. We know how to prevent it.

For many years, we knew how to treat pernicious anemia, long before we learned exactly what it was in vitamin B-12, long before we knew there was vitamin B-12. I think that the discovery of the cause of pellegra in the 1920's, which really started off much of our current scientific advance, was made by learning what people were eating in the South long before we knew about the various B vitamins.

There is much that can be learned. I do not have to know how vinyl chloride causes the sinusoidal cells of the liver to end as angiosarcoma and kill the person, but we know how to keep people from being exposed to vinyl chloride. Both areas of research are important, not only one, not only the other. I suggest that the approach to prevention which your bill emphasizes is a major direction in which to go, while the basic research is also being done. Perhaps we will reach the Holy Grail of knowledge of mechanisms before we prevent all cancer. If not, I would rather prevent all cancer and leave the discoveries for some other, academic time.

Mr. MAGUIRE. Does the retinoic acid work only if it is active prior to the triggering of the tumors or is it something that would work to actually reverse the tumorogenic process once it had been initiated?

Dr. SELIKOFF. It does not seem to be in terms of reversal. That would be a therapeutic drug. This is in terms of prevention.

Mr. MAGUIRE. So you would have to get it to people before the cancer-causing substances to which they had been exposed actually triggered the carcinogenic reaction?

Dr. SELIKOFF. Yes, sir.

Mr. MAGUIRE. Is the same true of the immunological approach or does it reverse an ongoing process?

Dr. SELIKOFF. That might do both. We don't know. Research is currently under way to explore that difference.

Mr. MAGUIRE. There is one other question I would like to ask both of you. How do you feel about the feasibility of NCI establishing an integrated data base or registry to assist Federal, State, and other appropriate agencies in locating persons exposed to carcinogens and referring them to appropriate agencies and facilitating studies of the effects of carginogenic substances on populations? A tumor registry, in short. Is that a useful approach, or would you feel that data organized by geography would give us essentially the same answers and we might save the expense of a tumor registry?

Dr. SELIKOFF. At the moment, our experience with tumor registries has not been very sanguine, and unless advances are made, I would suggest our money might be better spent in other ways. Also, I believe that current progress being made in the National Center for Health Statistics be allowed to continue a bit to see what will result from their reorganization in this direction, and that the matter be reconsidered.

Mr. MAGUIRE. Dr. Highland, do you have a comment on this?

Dr. HIGHLAND. No.

Mr. MAGUIRE. Thank you very much for your testimony, gentlemen. The committee appreciates your participation. We will recess until 2 p.m. for the next panel.

Dr. SELIKOFF. Thank you.

[Whereupon, at 12:35 p.m., the subcommittee was recessed, to reconvene at 2 p.m. of the same day.]

AFTER RECESS

[The subcommittee reconvened at 2 p.m., Hon. Paul B. Rogers, chairman, presiding.]

Mr. ROGERS. The subcommittee will come to order, please. We are continuing the hearings on the biomedical research training amendments of 1978, and all similar identical bills.

We are pleased to have a distinguished panel to begin our testimony this afternoon: Dr. W. Gerald Austen, Churchill professor of surgery, Harvard Medical School, and chief of surgery, Massachussetts General Hospital, and member of the American Heart Association; Dr. Leonard S. Dreifus, F.A.C.C. president-elect, American College of Cardiology; Dr. Isadore Rosenfeld, associate clinical professor of medicine, and a member of the Citizens' Committee on High Blood Pressure; and Eliot Corday, who is a clinical professor of medicine at the University of California at Los Angeles.

We welcome each of you, gentlemen, to the committee. We are very pleased to have you here. We appreciate your presence here. Your statements will be made part of the record in full, and you may proceed as you desire.

STATEMENTS OF W. GERALD AUSTEN, M.D., PRESIDENT, AMERICAN HEART ASSOCIATION; ELIOT CORDAY, M.D., CLINICAL PROFESSOR OF MEDICINE, UNIVERSITY OF CALIFORNIA AT LOS ANGELES; LEONARD S. DREIFUS, M.D., F.A.C.C., PRESIDENT-ELECT, AMERICAN COLLEGE OF CARDIOLOGY; AND ISADORE ROSENFELD, M.D., CLINICAL ASSOCIATE PROFESSOR OF MEDICINE, CORNELL UNIVERSITY MEDICAL COLLEGE

Dr. AUSTEN. I am Dr. Austen, and I am currently president of the American Heart Association. I am particularly pleased to be here today. First for the honor, second because I carry good news. The death rate from heart disease is on the decline in all segments of our society—men and women, young and old. In large measure, this dramatic reduction, for example, a 14-percent reduction in the death rate from heart attacks in just the last 5 years, is attributable to the long-range commitment to the funding of basic research by the Congress, which then translates into education and prevention.

I come before your subcommittee to support your bill, H.R. 10908, the Biomedical Research and Research Training Amendments of 1978. On behalf of the 40,000 scientists and over 2 million lay volunteers of the American Heart Association, I would like to address my remarks to titles II and IV of the legislation.

In title II, to extend the National Heart, Blood Vessel, Lung, and Blood Act, we are greatly encouraged by your provision for a 3-year extension. We would like to emphasize that we believe the institute has suffered too long with a year-to-year authorization, and it is time for a longer authorization period for stability's sake alone.

We support the 3-year authorization levels for control and prevention programs under section 414 of the Public Health Service Act, slated for $40 million in fiscal year 1979, $45 million in fiscal year 1980, and $50 million in fiscal year 1981.

These are reasonable year-to-year increases in extremely valuable prevention programs such as the hypertension education program at the National Heart, Lung, and Blood Institute. The amendments concerning increased emphasis on diet, nutrition, and environment education are especially welcomed by the American Heart Association. The directive to the Heart, Lung, and Blood Centers to engage in professional and public education programs is a positive proposal we support.

Our only problem with title II of H.R. 10908 is the level of authorization for the 3-year period. Basic research in cardiovascular disease has been on the decline each year for the past 7 years.

In 1970, heart disease research received 73 percent of the National Heart, Lung, and Blood Institute's funding. In 1977, that percentage fell to 57 percent. This dramatic 16-percent decline was a result of several factors. Perhaps the most important was the diffusion of the National Heart, Lung, and Blood Institute's mission by the addition of new responsibilities without a corresponding increase in appropriated funds.

H.R. 10908, for example, includes additional responsibilities for the Institute, but the authorization level covers really only the cost of part of inflation, with a very modest increase for anything else.

Our estimate is that the proposed authorization of $460 million will really not cover in any way the present operations of the Heart, Lung, and Blood Institute. I might indicate that the present authorization for the present year has allowed approximately 40 percent of the approved, new grants to be funded.

If the $460-million appropriation that the administration has suggested were enacted, our estimate would be that funding of approved grants, namely, grants that are considered worthwhile, would drop to 19 percent.

To keep it at what we would consider an unsatisfactory 40 percent, would require about $60 extra million, namely, to go up to $250 million, counting the control programs that we have already talked about.

I guess that it really gets down to where you consider the proper cutoff point is in terms of important and worthwhile research. Because if you approve it and do not fund it, you might as well not approve it in terms of what it does for the institution and for the people of this country.

Mr. Chairman, in spite of the fact that in 1975, for the first time since 1967, the number of deaths from cardiovascular disease dropped below 1 million, cardiovascular disease still accounts for over 50 percent of all deaths in America.

We, in the American Heart Association, believe that there should be more research support for heart disease rather than less. We, therefore, respectfully urge the subcommittee to amend the authorization figures for fiscal year 1979 from $460 million to $540 million, and for fiscal year 1980 from $505 million to $650 million, and for fiscal year 1981 from $550 million to $750 million. The authorization figures should be viewed as a reasonable ceiling, not as a floor.

Mr. Rogers, as you know, in recent years the American Heart Association has presented a budget recommendation based on what we hope have been careful considerations and justifications. As America's largest volunteer health consumer advocate group, we hope that we have been responsible.

We honestly feel that the numbers that we are talking about are minimum. We are very anxious to recommend those numbers, and to defend them here, and also in the Appropriations Committee, when they occur.

We want to give you the highest possible compliment that we can on your 3-year extension proposal of the National Research Service Awards Act, which is title IV in your bill. As you know, it is imperative that we provide for an adequate supply of researchers for their are really fundamental to what H.R. 10908 is about.

The 3-year extension will add stability and continuity to this important research training law.

The five amendments to the National Research Service Awards Act have the strong endorsement of the American Heart Association. The changes in the service requirements for National Research Service Awards support are reasonable. The amendments changing payback credit and the months of alternative service appear to be equitable for both the program and the trainee. The amendment providing for cost-of-living increases is long overdue in our inflationary society. We are particularly pleased about the amendments which lengthen the predoctoral training support from 3 to 5 years, and the percentages mandated for training grants, 50 percent and direct fellowships, 15 percent.

I think that I can cut my talk short by saying that we are in agreement with those five amendments, and that we think they are excellent.

The American Heart Association strongly supports the substantive changes proposed for titles II and IV of H.R. 10908. It is our hope that you will consider the recommended changes in the authorization levels for the National Heart, Lung, and Blood Institute under title II as proposed by the American Heart Association.

Thank you.

Mr. ROGERS. Thank you very much, Dr. Austen.

STATEMENT OF ELIOT CORDAY, M.D.

Dr. CORDAY. Mr. Rogers, and Dr. Carter, I am Eliot Corday. I am a practitioner, researcher and teacher. I am clinical professor of medicine, UCLA School of Medicine, chairman of the cardiac care committee, Cedars-Sinai Medical Center, and national consultant to the Surgeon General, U.S. Air Force. I am author of some 329 publications and 7 monographs on the cause, management and prevention of heart disease. I appear before you to recommend passage of H.R. 10908 for May 1978, for continuing of the 3 year period, and to plead that your committee provide a more appropriate authorization to fund basic cardiovascular research.

I am concerned that the authorization proposals by the administration for 1979 are less than they were when the act was passed in 1972. I am also alarmed that the proposed level of funding will only allow payment of 19 percent of all projects that have competed and have such promise that they have been approved by study groups for funding. Traditionally the institute was able to fund 80-90% proposed projects. These exciting research opportunities are being stifled by budgetary constraints that exceed those that existed when the first heart act was passed.

I would like to show you this graph, if I may. These—thin solid line—are number of applications received by the National Heart, Lung, and Blood Institute. As you notice, as the years go along, from 1964 to 1978 they have increased very much particularly in the past 2 years. However, if we look at the approvals—dotted line—they have also increased but the percent of approvals awarded—solid line—are dropping down to 19 percent of all grants that have been approved. In other words, we are cutting off our research effort. We are stifling the research effort.

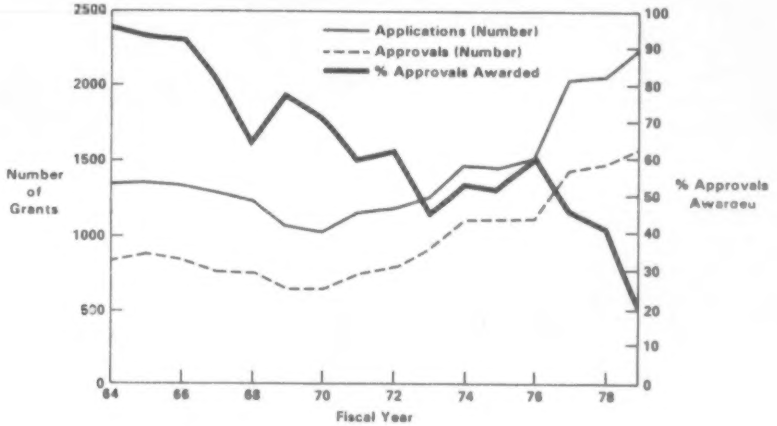
I am terribly alarmed that we are going to lose our tremendous human resources that we have trained at great expense. It is really a catastrophe, sir.

If I may submit this for the record.

Mr. Rogers. It will be received.

[The following chart was received for the record.]

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
REGULAR RESEARCH APPLICATIONS
NUMBER OF REQUESTS AND APPROVALS vs. PERCENT AWARDED



Dr. Corday. I humbly recommend that the NHLBI authorization for 1979 provides: An additional $100 million for cardiovascular research of which $54 million would be identified for new basic research which will develop more effective prevention programs, and $46 million to fund research projects which have been approved but cannot be funded.

An additional $20 million for research on sudden cardiac death.

An additional $30 million for targeted studies to determine if expensive rehabilitation programs are effective and cost beneficial to provide noninvasive techniques for detecting occult coronary disease. In other words, I recommend an authorization for the NHLBI of $595 million for the year 1979; $680 million for the year 1980, and $800 million for the year 1981.

The existent Heart Act demands that 30 percent of the NHLBI budget must be identified for Lung and Blood. Because of my experience as a member of the Advisory Council of the NHLBI—(1967–72)—I am of the opinion that Lung and Blood already have adequate funding and therefore recommend that the proposed increased appropriation of $150 million for NHLBI not be strangled by removing 30 percent for these two categorical diseases.

We all recognize that cardiovascular disease continues to be our nation's greatest killer, accounting for 994,513 deaths, that is 52 percent of all deaths. Cardiac and cerebral vascular disease is responsible for the major expenses for health care delivery and disability pensions. We have seen breakthroughs thanks to the previous directions and appropriations of the National Heart Act. We are grateful that hypertension is now under control, and new methods have been developed for the better care of the coronary victim which have reduced the annual mortality rate dramatically.

When I served on the National Advisory Heart Council we reviewed the present status of cardiovascular disease several times each year. It became evident to me that if we hope to conquer this dreaded ailment which sweeps many away in the prime of their lives, we must provide a more adequate prevention program against arteriosclerosis and sudden cardiac death. I feel that a stepped up research crusade could be meaningful because in my lifetime I have encountered great conquests against devastating disease processes which used to pillage the nation. For instance, at the time of my graduation I could not envision how tuberculosis, poliomyelitis, and infections could be conquered. We believed it was the will of God. Tuberculosis which was so costly, infectious and treacherous no longer is a significant threat from the public health standpoint. Poliomyelitis used to hang over our heads in the summer and fall and we physicians felt so helpless as we watched it spread across the Nation claiming hundreds of thousands of young people. Thanks to your congressional appropriations that enabled Enders to isolate and grow the virus, and Sabin and Salk to develop specific vaccines this unbelievable destructive disease has been conquered.

THE RESEARCH CONTRIBUTIONS OF THE NIH HAVE SAVED LIVES AND HUMAN SUFFERING, REDUCED HEALTH CARE COSTS, INCREASED GROSS NATIONAL PRODUCT AND AUGMENTED TAX ROLLS

As a student before the Second World War, I recall how I feared infections which might result in a person's death within a matter of 48 hours due to a minor wound infection, or what we called blood poisoning. Now I must tell you this is a different world—I can hardly believe that infectious diseases have been conquered by specific antibiotics. Heart surgery was not considered possible until 1952, and now, although we cannot prevent heart disease, our surgeons are able to "patch up" the disease process. These are just a few of the great conquests which have been resolved by congressional direction, along with a proper appropriation directed through the NIH. Our competitive free enterprise system where scientists have the freedom to study, allows them to accomplish the impossible.

We are thrilled that due to your efforts, at last we can report that the mortality rate of cardiovascular disease declined somewhat in the past decade from 55 down to 52 percent of all deaths. Many feel this reduction in mortality is principally due to control of hypertension, better emergency care systems for the coronary victim, and the benefits of cardiac valvular, bypass or abdominal aneurysm surgery. We must appreciate the facts that through your encouragement, appropriations and research opportunities, our dedicated scientists have accomplished a tremendous victory over disease.

But, despite the magnificent contributions in biologic research of acquired degenerative and congenital diseases of the past three decades, I feel that we must recognize that arteriosclerosis continues to plague our citizens by reducing their lifespan and costing fantastic sums of money for health care delivery and disability pensions. We also realize that such disability reduces our gross national product and thus depreciates the tax rolls. A horrendous mortality due to cardiovascular disease continues, so that our fight to contain the Nation's greatest killer remains our No. 1 health problem.

WHAT HAS CAUSED THE STIFLING CUTBACK IN BASIC CARDIOVASCULAR RESEARCH?

We learn that the present National Heart Lung and Blood Institute budget can only support 19 percent of all research grant proposals which have been approved for funding at the last National Advisory Heart Council meeting after a stiff national competition. This compares to a level of 60 to 90 percent in previous years. However, the NHLBI budget seems to be larger than ever—why then doesn't our 1978 authorization provide sufficient funding for research? This has come about because of the whole 1978 NHLBI budget of $448 million, an act of Congress has authorized that 30 percent—or $150 million of the budget—had to be directed to two other disease entities—Lung and Blood, and another $35 million was earmarked for ongoing cooperative clinical trials which are meaningful. That leaves about $218 million for heart research—and that is about the level of funding available in 1967. About $180 million is committed to continuing studies, and that leaves only a meager $38 million to fund new basic investigator initiated cardiovascular investigations. We all know that inflation has eroded away that dollar value so that ingenious research opportunities have to be seriously constrained and laboratories will be shut down across the Nation.

STAGGERING HEALTH CARE COSTS WILL BE REDUCED BY PREVENTATIVE HEALTH PROGRAMS

I can foresee that with specific appropriations spread over a continuous period of 3 to 5 years, our Nation stands a very good chance of establishing a program of prevention which could reduce the staggering health care costs required to patch up the injury created by arteriosclerosis. When proper prophylactic health measures are implemented, I am sure they will improve the nation's health, increase the gross national product, reduce disability payments and swell the tax rolls.

THE NEED FOR MORE EFFECTIVE PROPHYLACTIC MEASURES WHICH WILL PREVENT CARDIOVASCULAR DISEASE

Many believe that the medical profession already knows enough of the answers to the problem of the aging process, and that all they have to do is have everyone apply the present principles of risk factor intervention, and the Nation would no longer suffer from cardiovascular illnesses. But I must point out that recent reports by world authorities like Sir John McMichael, Nemat Borhani, Ahrens, Mann, and Kannel have cast doubt on the possible benefits of present day interventions. Kannel, a principal architect of the "Framingham Study" which established coronary risk factors stated:

> There are few prophylactic measures of proved efficacy in coronary heart disease. This applies to primary and secondary prevention. Neither hygienic, pharmacologic nor surgical measures have been shown conclusively to delay acute episodes or to prolong life.

A recent editorial in Lancet casts this doubt:

> So far, despite all the effort and money that have been spent, the evidence that eliminating risk factors will eliminate heart disease adds up to little more than zero in terms of preventing heart disease on a public health scale.

And our Food and Drug Administration has, in effect, formalized these doubts by demanding that advertisements for certain lipid-reducing drugs carry this qualifying codicil:

> Important Note: It has not been established whether drug-induced lowering of serum cholesterol and other lipid levels has a detrimental, a beneficial, or no effect or morbidity or mortality due to atherosclerosis or coronary heart disease.

Prominent investigators have reinvestigated the diet-heart questions, the effects of exercise, smoking, diabetes, cholesterol, phospholipids, and low vital capacity. It would now appear that only hypertension, smoking, and lipids may play a role. There is general agreement that an association exists between certain risk factors and the occurrence of arteriosclerosis, but doubt exists that interventions will reverse the aging process except possibly in the case of hypertension, lipids, and tobacco. There is some evidence that control of hypertension has provided a great step forward which has affected the mortality rate. Because single risk factor interventions have failed to control the arteriosclerotic process, a blue ribbon task force of the NHLBI in 1971 formulated the concept that if the three principal risk factors: Hypertension, smoking, and diet which stood out statistically as being of higher risk, that control of all three at one time stood a better chance of affecting the arteriosclerotic process. The NIH followed their recommendations and instituted the costly multiple risk factor trials—(Mr. Fit)—which are now taking place as a cooperative program across the Nation. The answers to this very important clinical trial program will be concluded in the year 1982 and we eagerly await the answers.

But, there is increasing evidence from the publications of our scientific leaders that correction of risk factors in themselves does not seem to solve all the problems. We hear them state that at best, if we could control the lipid problems it would apply to only 3 to 8 percent of the overall problem. We read statements of the Director of the NHLBI who happens to be one of the great scientific leaders in the lipid field, that once the arteriosclerotic disease process becomes clinically evident, there is little evidence that interventions will affect the diabolic onslaught of the destructive arteriosclerotic disease process.

A massive clinical trial involving some 12,000 human subjects was designed to test the effect of lipid lowering drugs on the death rate of patients with obstructive coronary lesions. However, trial of lipid lowering drugs used as a standard in clinical practice such as premarin, nicotinic acid, atromid, and thyroid derivatives, suggested that these agents were either dangerous or totally ineffective in preventing a first heart attack or deaths from coronary disease. Although some criticize that this massive study cost some $40 million, we must appreciate that the answers had to be known. The annual sale of these drugs which proved to be ineffective were many times the annual cost of the study.

Although the practitioners are pleased to hear the plea from congressional leaders to go ahead and implement preventive measures, they become frustrated because, except in the case of hypertension, they in all honesty do not know enough to convince their patients to change their lifestyle. Unless the practitioners have confidence that with a fair degree of certainty preventative measures will provide positive results, it would be wrong for Congress to demand them to implement questionable procedures. Simply speaking, it appears to me that medical politic is not convinced that today's lipid lowering drugs or any other interventions are either feasible or effective in reducing the incidence of coronary heart disease in the general public. Let's face the truth that although a prudent diet, exercise, control of blood pressure, and cessation of the smoking habit would do no harm, we simply don't know enough to categorically promise they can stem the terrible onslaught of arteriosclerosis.

The NHLBI task force on arteriosclerosis of 1971 pointed out that we still do not know the cause of the obstructive arteriosclerotic process, and that much more basic research is needed. Imaginative investigators might well look for other likely causes of arteriosclerosis that, when identified could be investigated thoroughly by a disciplined program managed by leading scientists of the world, brought together in specialized centers. Such programs could be fashioned and financed with the same sense of urgency with which our nation dramatically pursued the atomic energy and space programs. However, these successful efforts were perhaps better supplied with the basic information necessary to formulate and execute a productive program. In physics, for instance, it was Einstein's famous equation $E=mc^2$ that provided a major step toward the development of nuclear energy. We must ask if in cardiology we have some formulae which have such promise.

PROMISING NEW DIRECTIONS FOR THE PREVENTION OF CARDIOVASCULAR DISEASE

There now appears to be some new information which might provide a tentative formula for the basic genesis of the arteriosclerotic lesion and its prevention. There are 11 points of interest that might supply some of the answers for a more effective public health care policy. We advocate the following new directions:

NEW CONCEPTS IN LIPID ANALYSIS

It is evident from numerous studies that many patients who suffer severe arteriosclerosis of the peripheral blood vessels which result in coronary and cerebrovascular disease appear to have normal lipid patterns. Most agree that about 75 percent of coronary and cerebral stroke victims have blood cholesterol and other lipid fraction levels that seem to be normal. However, more recent studies demonstrate that patients who are stricken have an elevated blood lipid fraction designated as low density lipoproteins. It is also known that the high density lipoproteins seem to be associated with a lesser degree of arteriosclerosis. All agree these exciting basic research investigations demand a new research thrust to determine whether these lipid fractions can be affected either by pharmacologic or dietary methods to provide a more rational and successful basis for prophylactic care.

METABOLIC ERRORS OF THE VESSEL WALL

Little is known about the metabolism of the wall of the blood vessel. Such basic knowledge is urgently needed because it could explain the cause and prevention of arteriosclerosis.

ENDOCRINOLOGY

Endocrines should be incriminated as a cause of arteriosclerosis because it is obvious that most women do not develop clinical manifestations until after their menopause. National statistics continue to demonstrate that women survive an average of 9 years longer than men. Could it be that the pituitary, gonads, or other endocrine organs play an etiological role and that, if they can be earmarked, they could supply preventative measures.

IMMUNOLOGY

Heart transplant surgeons noted that a youthful donor's heart after transplantation develops premature arteriosclerosis which seems to progress at a galloping pace to obstruct the coronary arteries and kill the patient within a few years. We should not anticipate for a moment that all cases of arteriosclerosis are due to immunologic phenomena or rejection phenomena, but it does suggest that heart transplantation could offer a rapidly advancing model for the study of the mechanisms which might be incriminated and attacked.

Lupus erythematosus has also been shown to cause premature fatal coronary attacks due to atherosclerosis in afflicted women before they reach 20 years of age. Comprehensive study of the immunologic processes in such rapidly advancing models might provide more meaningful preventative measures for the broad spectrum of the destructive arteriosclerotic process.

FAMILIAL CORONARY DISEASE

Families have been identified where all the males die before they are 40 years of age, and yet present preventative measures failed to affect the course of the arteriosclerotic process. Study of such an accelerated familial disease state might provide a model that could offer fruitful investigations.

ENVIRONMENTAL INFLUENCES

It is very difficult to obtain sharp endpoints for scientific investigations of such matters as emotional influences and personality as a cause of arteriosclerotic disease. Scientists have noted that people who were confined to concentration camps, upon their release in subsequent years deevloped premature coronary or cerebrovascular disease. Comparative in depth social, psychological, and dietary studies of the survivors with those of their kin who were not imprisoned, could provide meaningful data on which environmental factors influence arteriosclerosis, and this could lead to possible methods of prevention and treatment. But these survivor studies must be implemented soon, before the remaining survivors succumb.

HYPERTROPHY OF THE SMOOTH MUSCLE

Recent investigations have indicated that an overgrowth of the smooth muscle lining of the arterial wall leads to accelerated atherosclerosis. This mechanism requires intensive investigation because it could lead the way to breakthroughs in the cause and prevention of our greatest killer.

THROMBOSIS AND FIBROLYTIC MECHANISMS

Our knowledge of the role of clotting mechanisms within the blood vessel as a cause of arteriosclerosis must be amplified because it appears to play a principal role in the formation of the aging process.

RENAL DIALYSIS

Young patients who have been treated with renal dialysis appear to develop serious coronary disease prematurely. These subjects could provide an accelerated model for investigations in preventative measures.

DIABETES

The arteriosclerotic process may advance in diabetics despite the control of the blood sugar level. Possibly somatostatin, a naturally occurring growth hormone, recurrent hypoglycemia, or some unknown factors might be incriminated and provide meaningful solutions.

GENETICS

Most agree that genetics play the major role in the arteriosclerotic process. Now that genetic engineering seems possible, major research into the relationship of genetics and heart disease is vitally needed.

WILL MR. FIT PROVIDE THE FORMULA FOR PREVENTION

As we have stated, clinical trials with single risk factor interventions have failed to provide adequate prophylaxis. We hope that the Mr. Fit trials will provide the answer to whether application of multiple risk factor intervention (Mr. Fit) will be of benefit. However, we must face the fact that if these multiple risk factor trials do not prevent the progress of arteriosclerosis, our health planners may be faced with a sort of scientific bankruptcy.

We all know that in planning for the defense of a country that the military plans for all future eventualities including failure. The scientific community should also have plans under way in case the Mr. Fit fails to provide a defense against the Nation's biggest killer.

NEED FOR A PROPER APPROPRIATION ON PREVENTATIVE MEASURES

I appeal to this congressional committee to realize the need for a more adequate appropriation of $595 million a year for new investigations that might provide for a preventative war against our Nation's greatest killer. With a proper appropriation continuing for a 5-year period, the Nation has an excellent chance of providing a more rational preventive care program. With encouragement by Congress, the scientific community will rally to the cause, and I feel certain that if we will provide the tools for our great scientists they will complete the job. This is a small investment compared to the benefits which will accrue. In the long run it will more than pay the initial expenses by reducing both health care costs and disability income and in the end will increase tax rolls. Of course, it is impossible to equate the actual dollar savings which will accrue by saving some hundreds of thousands of lives each year, and by reducing human suffering.

CONCLUSIONS

I am not speaking on this great issue because I have a vested interest. My research endeavors do not and will not take me into this very sophisticated area. I as a practitioner and research investigator am constantly asked by my patients what I advise for prophylaxis. I find it very painful to have to tell them that after all these years we are not too sure about whether strict adherence to the risk factors will affect their longevity. I have seen hundreds of thousands of people in my 40 years of practice and still am not convinced that strict adherence to the risk factor admonitions affects longevity.

I appeal to Congress to provide a more appropriate level of funding to keep cardiovascular investigators at their benches so that they can continue to provide dramatic patch-em-up techniques for the afflicted and interventions to reduce sudden death for some 300,000

U.S. citizens each year. Basic research might provide such startling answers that even our most enlightened health planners cannot envision.

This, my dear Congressmen Rogers, is the American Dream. Please look over the price list and realize that it is an affordable investment and will, in the long run, not cost the taxpayer, but will offer them relief from their staggering burden.

I, therefore, recommend that a budget of $595 million be appropriated for the coming year, so that we may start our conquest of this dread disease of arteriosclerosis, particularly.

Mr. ROGERS. Thank you so much, Dr. Corday.

STATEMENT OF LEONARD S. DREIFUS, M.D., F.A.C.C.

Dr. DREIFUS. I am Dr. Leonard S. Dreifus from the Department of Cardiovascular Diseases the Lankenau Hospital, Philadelphia, Pa. I am also the president-elect of the American College of Cardiology. It is in this capacity that I submit the following remarks [see p. 193].

Before addressing the specific details of the "Biomedical Research and Research Training Amendments of 1978," I would like to express the College's support for the activities of the National Heart, Lung, and Blood Institute. In Institute Director, Dr. Robert Levy, the NHLBI has a dedicated leader, an eminent scholar, and a capable and imaginative administrator.

I would like to reflect and give my great thanks to all of those investigators and scientists that have been able to achieve this 14-percent reduction in deaths from heart attack. We are now beginning to see the light at the end of the tunnel in reducing deaths from heart disease.

Again, I reiterate that deaths due to heart attack represent still 50 percent, or a little bit more, of deaths in this country, and something should be done about it. There is a tremendous financial loss as well as all the humanities and losses that we now recognize.

I would like particularly to commend you, Mr. Chairman, on introducing H.R. 10908, providing for a 3-year extension. Again, the 3 years offer continuity. It offers the investigator really an unprecedented way to begin to continue the research. The 1 year, of course, would do very little to give him that continuity to research subjects, and to reap the rewards, to do the experiments that will lead to the payoff in this type of research.

We would like to recommend the authorization levels for a 3-year renewal. In these recommendations, let me point out quickly that the college has acted in restraint, understanding the economic burdens in this country in many other sectors.

It is with this type of restraint, and I hope enthusiasm, and imagination that these figures would be recommended. In fiscal year 1979, $540 million for research and training programs and $40 million for prevention, education, and control programs.

For fiscal year 1980, $605 million for research and training programs and $45 million for prevention, education, and control programs.

For fiscal year 1981, $665 million for research, training programs, and $50 million for prevention, education, and control programs.

It was pointed out and I will clearly reiterate it, unless we come to these levels, it is a simple matter of mathematics that we will only be able to take care of 94 percent of existing commitments in fiscal year 1979.

In addition, with the increase of at least 25 percent in new research applications, which really reflect enthusiasm and imagination and great talent, where investigators see a need to move ahead, we would probably be able to only fund 16 percent of those grants, which were submitted.

In the committee report which accompanied H.R. 4975 last year, the committee reaffirmed the need for an expanded, intensified and coordinated program for heart, blood vessel, lung, and blood diseases as mandated by Public Law 92–423 in 1972 and Public Law 94–278 in 1976.

I think that I should point out, Mr. Chairman, that if we are to achieve equal access to medical care in this country, we can no longer engage in treating disease. We must engage in preventing disease, if we are to achieve this American dream of equal access under the law.

This is again a plea for the justification of our authorization levels. We would also like to plead that the authorization levels represent an opportunity level rather than a restricting level, which would be a problem for achieving proper funding for the necessary projects.

Finally, I would like to state for the record our support for the amendments in H.R. 10908 which would expedite the training mission of the NHLBI, and would encourage speedier dissemination of research information to health professionals. We feel that this has been a great contribution.

Mr. Chairman and distinguished members of the subcommitee, on behalf of the American College of Cardiology, I wish to express our greatest gratitude for having invited us to present our views on this extremely important subject.

Thank you.

[Testimony resumes on p. 199.]

[Dr. Dreifus' prepared statement follows:]

STATEMENT OF LEONARD S. DREIFUS, M.D., F.A.C.C.
PRESIDENT-ELECT OF THE AMERICAN COLLEGE OF CARDIOLOGY

Mr. Chairman and Members of the Committee:

I am Dr. Leonard S. Dreifus, Department of Cardiovascular Diseases, The Lankenau Hospital, Philadelphia, Pennsylvania. I am also the President-elect of the American College of Cardiology; it is in this capacity that I submit the following remarks.

The American College of Cardiology is a professional, medical-specialty society of more than 8,500 physicians and scientists who specialize in heart disease and other closely related disorders.

Before addressing the specific details of the "Biomedical Research and Research Training Amendments of 1978", I would like to express the College's support for the activities of the National Heart, Lung, and Blood Institute. In Institute Director, Dr. Robert Levy, the NHLBI has a dedicated leader, an eminent scholar, and a capable and imaginative administrator. As your Committee noted in H.Rep. 95-381:

> The Committee is generally pleased, given the current resources of the National Heart, Lung, and Blood Institute, with the accomplishments of the National Heart, Blood Vessel, Lung and Blood Disease Program. Testimony before the Subcommittee on Health and the Environment revealed that from 1970 to 1975 deaths from heart attack declined 14 percent. This corresponds to a decline of less than 7 percent for all other causes of death. The decline for coronary heart disease (heart attacks) is particularly significant since until relatively recently, the number of deaths was increasing and since mortality from this disease accounts for almost two-thirds of all deaths from cardiovascular disease . . . It is estimated that 49,000 fewer deaths from cardiovascular disease occurred in 1976 compared to 1974. This savings in lives alone is greater than the number of lives that could be saved if all deaths from automobile accidents could be avoided! . . . However, despite these decreases, cardiovascular diseases still account for 52.5 percent of all deaths in the United States. This is an overall decline from 54 percent of only a few years ago.

Dr. Levy, the Institute, the National Heart, Lung, and Blood Advisory Council, and, indeed, our own membership, take great pride in being able to cite these impressive achievements in combating cardiovascular disease.

The College is appreciative of this Committee's efforts to continue the existence of this important Institute, and Chairman Rogers should be highly commended for introducing H.R. 10908, which provides for a three-year extension of appropriations authorizations for the National Heart, Lung, and Blood Institute. As you know, the Senate counterpart to this measure (S. 2450) provides only a one-year extension of appropriations authorizations for this vital Institute. The American College of Cardiology considers that a one-year extension would be a severe handicap to the successful and necessary programs of the NHLBI.

In 1972, the NHLBI authorization was wisely extended for three years. This was followed by a two-year renewal from 1975-1977, an exception to the original three-year allowance so that the activities of the National Program would continue without interruption subject to a later review by the President's Biomedical Research Panel. The 1977 renewal legislation of one year was yet another exception to the original three-year renewal. In our testimony presented before the Committee a year ago, the American College of Cardiology was fully supportive of this one-year renewal because Congress desired to cooperate with the new Administration and wanted to assure that the Institute function smoothly prior to the consideration of legislation to substantially revise the Institute's programs. However, we cannot now ascertain a satisfactory rationale for yet another one-year extension.

The unstable and unpredictable atmosphere generated by repetitive one-year renewals, could have deleterious effects on the Institute's ability to carry out its Congressional mandates.

The American College of Cardiology is in complete agreement with your decision to recommend a three-year extension of the legal operating authorities of the NHLBI: it demonstrates wisdom and foresight. A three-year extension would assure the continuity, stability, and effective planning of its heart, lung, and blood research and training activities; moreover, it would conform to HEW's recommendation.

While the American College of Cardiology is sincerely grateful for your recommended three-year authorization extension for the National Heart, Lung, and Blood Institute, the College respectfully recommends higher authorization levels than those included in H.R. 10908. The College's recommended authorization levels for this three-year renewal period are:

FY 1979:	$540 million for research and training programs $40 million for prevention, education and control programs
FY 1980:	$605 million for research and training programs $45 million for prevention, education and control programs
FY 1981:	$665 million for research and training programs $50 million for prevention, education and control programs

The College is concerned that, at the authorization levels of $500 million, $550 million and $600 million for Fiscal Years 1979, 1980 and 1981, the Institute will find it difficult, if not impossible, to initiate new research and training programs while at the same time meeting its existing commitments.

For example, the Administration's FY 1979 authorization request for the Institute is $432.2 million. Such an allocation would represent a significant decrease below FY 1978 levels. It would allow the Institute to meet only 94% of its existing contractual commitments. Moreover, it would provide for the funding of only 16-19% of approved new and competing research grants; this corresponds with a 40-50% rate of funding achieved in recent years. To compound this problem, we would like you to be aware of the fact that the Institute has received approximately 25% more research grant applications in FY 1977 than in FY 1976. These two phenomena spell an increased enthusiasm in the scientific community to participate in the biomedical research programs of the NHLBI but less money available for the Institute to meet this challenge.

In the Committee Report which accompanied H.R. 4975 last year, (H.Rep. 95-117), the Committee reaffirmed the need for an expanded, intensified and coordinated program for heart, blood vessel, lung, and blood diseases as mandated by P.L. 92-423 in 1972 and P.L. 94-278 in 1976. However, for the Institute to continue its important activities and to embark upon new programmatic opportunities, authorization levels must be greater than the Administration's budget request and greater than the funding levels proposed in H.R. 10908.

Further, there is another very important reason for setting higher authorization levels for the research and training programs --- a rationale that reflects the realities of the appropriations mechanism. Recent experience has shown that authorizations often are interpreted as exaggerated ceilings by the Appropriations Committees; in other words, actual appropriations fall far short of authorizations. In FY 1973, about $400 million was authorized for the National Heart, Blood Vessel, Blood and Lung Program; only $280 million was appropriated. In FY 1974, $460 million was authorized and only $284 million appropriated. In FY 1975, there existed a $200 million gap between the two figures. While authorization levels should provide guidelines for Institute appropriations, room must be allowed for new initiatives in promising program areas as well as for continued funding of the present programs at current inflationary rates. Authorization levels should be sufficiently high to be perceived as opportunity levels rather than as having the effect of establishing a restrictive ceiling on the Institute's budget.

We believe that our recommended authorization levels reflect the careful balancing of fiscal restraint and the Congressional desire to support the activities of the NHLBI. At our recommended authorization levels, the National Heart, Lung, and Blood Institute will be given the necessary resources to pursue the comprehensive program strategy to promote research in, and prevent diseases relating to the heart, lungs, and blood.

Finally, Chairman Rogers, you are again to be commended for introducing H.R. 10908 because of the inclusion of two substantive and well-needed amendments to the National Heart, Blood Vessel, Lung, and Blood Act (P.L. 92-423).

The first of these modifications, recently recommended by the National Heart, Lung, and Blood Advisory Council (§202 of H.R. 10908) would require the transmittal of the Director's Report simultaneously to the President and Congress not later than November 30th each year. Current law provides for the submission of the Report "as soon as practicable after the end of each fiscal year" to the President for later transmittal to Congress. Last year, NIH appropriations hearings were held in February; although this comprehensive document could have been a valuable resource to the Members of Congress who determine how much funds should be allocated to the Institute, the Report was not released until July. The American College of Cardiology is in full agreement with your belief that these problems would be alleviated by adoption of this amendment.

The College also supports §203 of H.R. 10908 which amends §413(d) of the Public Health Service Act "to provide on a timely basis" for the dissemination of research information to the public and health professionals. Many of our members conduct cardiovascular research, and many more, as practitioners and educators, apply it to the treatment of patients. We can appreciate the need to transmit new knowledge "from bench to bedside". Accordingly, in conformance with the recommendation of the National Heart, Lung, and Blood Advisory Council, we welcome your statutory reference to the dissemination of information with minimal administrative delay.

In conclusion, may I reiterate our appreciation for your efforts to continue this vital Institute's activities. In a recent Presidential Proclamation, President Carter declared the month of February 1978 as American Heart Month. In the Proclamation, credit was given to the National Heart, Lung, and Blood Institute for its National effort to reduce illness, disability, and death from heart diseases through nationwide programs of biomedical research in the cardiovascular field, training of research personnel, and information and education programs for health professionals. President Carter also invited Congress and the Nation to join him in reaffirming our commitment to the search for new ways to prevent, detect and control cardiovascular diseases in all its forms. The American College of Cardiology perceives the pending legislation as an excellent opportunity for your Committee, as our country's pre-eminent health policymakers, to reaffirm your commitment and support for the National Heart, Lung, and Blood Institute by providing a three-year extension of authority at our recommended authorization levels.

Mr. Chairman and distinguished Members of this Subcommittee, on behalf of the American College of Cardiology, I wish to express our deepest gratitude for your having invited us to present our views on this extremely important subject.

Thank you.

Mr. ROGERS. Thank you very much, Dr. Dreifus.

Dr. Rosenfeld, you may be interested that Dr. deBakey has written the committee a letter saying that he had hoped to join us, but he was not able to. He said that Dr. Rosenfeld, who was an associate of his, was one of the most distinguished scholars, and had agreed to testify. He felt that it was important that the subcommittee hear from Dr. Rosenfeld.

Without objection, that letter will be made part of the record, and we welcome you.

[The letter referred to follows:]

CITIZENS FOR THE TREATMENT OF HIGH BLOOD PRESSURE, INC.,
Washington, D.C. February 22, 1978.

Hon. PAUL G. ROGERS,
Chairman,
House Subcommittee on Health and the Environment,
Rayburn House Office Building,
Washington, D.C.

DEAR MR. CHAIRMAN. I deeply regret that prior commitments will prevent me from testifying on Wednesday, March 1, on H.R. 10908, the legislation you introduced which includes a three-year renewal of authorizations for the National Heart, Lung and Blood Institute.

I want to commend you, not only for the introduction of this legislation, but for the fact that it authorizes appropriations for the ensuing three Fiscal years.

Doctor Isadore Rosenfeld, who is Clinical Associate Professor of Medicine at Cornell Medical College and one of the most distinguished cardiologists in the country, has agreed to testify on the Heart budget on behalf of Citizens for the Treatment of High Blood Pressure. Doctor Rosenfeld, a close personal friend of mine, has worked actively with me over the past five years in both the fields of hypertension and cardiology. Since hypertension comprises approximately 20 percent of research and training monies in the Heart area of NHLBI, I think that it is important for the Committee to hear from Doctor Rosenfeld.

The next time I am in Washington, I hope to be able to have a visit with you.

Cordially,

MICHAEL E. DEBAKEY.

STATEMENT OF ISADORE ROSENFELD, M.D.

Dr. ROSENFELD. I first want to identify myself with the remarks made by my distinguished predecessors. The facts and figures you have before you in the submitted testimony, I would like to make part of the record [see p. 203].

As a clinician, I would like to highlight the impression that your bill and its impact may have on American medicine.

I am very happy to be here. In my written comments, which are now part of the record, you will notice that I plan to limit my discussion to the field of hypertension and sudden death, two major areas in which I happen to have a particular interest.

Coming over here from the airport in a taxi, today, I was reminded of another problem, when I saw literally hundreds of joggers, some of them Congressmen and Senators, and other government employees, trotting around a body of water that leads to the Congress.

I hope that the appropriations, which we will be discussing at another time, will include ta definitive study to determine the actual magnitude of benefit and/or dangers of such activities. I suspect that they are beneficial. But the lives of Congressmen are too precious to take a chance on that.

Mr. **Rogers.** Unfortunately, this committee only provides authority for appropriations.

Mr. **Maguire.** If I might interject at this point, and indicate to the gentleman that if he has any indication that jogging is adverse in its effects on health, I wish you would inform the subcommittee as soon as possible because I jogged 6 miles yesterday, and I have not been out yet today.

I do want the record to show that I jog.

Dr. **Rosenfeld.** Mr. Chairman, I am sure that it must be very depressing for members of this committee, including Congressman Carter, and Congressman Maguire, to hear all the terrible things that are extant in this country with respect to diseases and morbidity, $50 billion in costs in treating cardiovascular problems alone.

Today, you have heard some good news from the president of the American Heart Association, Dr. Austen, when he talked about the decrease in mortality, with which we are all familiar.

But you know that you cannot talk in terms of these wonderful statistics as if they were a "fait accompli," and let's go on to something else, because the fact remains that 35 million Americans have hypertension.

As a result of the educational programs of the National Heart, Lung, and Blood Institute, there has been an increase in patient visits of 50 percent, seeking their physician to take their blood pressure, and there has been a 20-percent reduction in strokes.

However, all of this requires ongoing education, ongoing management, and leaves unsettled some very fundamental questions. I think that it would be wrong to get the impression that we have conquered hypertension.

There are great difficulties in compliance. I have great difficulty in getting many of my patients to continue to take the medication. We don't know, for example, what the impact is of giving these medications to young children, when we pick up hypertension in the prepubertal age. We are not sure about the significance of taking systolic hypertension alone in the very elderly, whether this has a positive or negative effect.

We don't even know whether it is necessary to reduce salt intake in order to prevent hypertension. We know that it is necessary to reduce it in treating it. But we don't know whether changing our salt eating habits will reduce the incidence of this disease.

There are many questions that remain unanswered on hypertension, and the National Heart, Lung, and Blood Institute has developed programs which require the appropriations and the 3-year authorization to effect.

For example, I was meeting with the Deputy Soviet Minister of Health the other day, and he outlined for me the program they have in the Soviet Union in which there is onsite identification and measurement of blood pressure in the major factories.

I have not seen this myself, but that is what he tells me, and I have no reason to deny its veracity. I am not familiar with any such program in this country. If we are going to identify hypertension early, and treat it effectively, we have to develop programs such as onsite measurements. We have to develop some methodology with regard to Blue Cross and Blue Shield, which will permit employers to devise a compensible method of "on-the-job identification programs."

So there is a great deal to be done in hypertension, even though the death rate from high blood pressure has been reduced by 80 percent.

I would like to now address myself to the question of sudden death. I don't think that it is really understood or appreciated, even in the medical community. Sudden cardiac death is the largest, most important public health problem in this country.

We are all emotionally involved with cancer, as we should be. We are emotionally involved with cancer of the breast, which causes 30,000 deaths every year. But, Mr. Chairman, there are approximately 450,000 people who die suddenly, just like that, in the United States every year.

We have an enormous problem in terms of identifying these people, and once having identified them, developing techniques to prevent their sudden death. We have come some way with long-term monitoring, and picking up people at high risk. We can sometimes predict sudden cardiac death. But we have very few drugs that we can give people that are well tolerated, and will predictably reduce the numbers of sudden deaths.

This is one of the enormous problems of American medicine, to which NHLBI is addressing itself, and it must have the 3-year authorization, and the appropriation with which to do it.

You may have read 2 weeks ago in the newspapers about the use of Ampurin, which is antigas medicine. I have been flooded with telephone calls. There are some questions that have been raised about certain aspects of this study. I don't think, on the basis of the information that has been made available, that I can give an answer to my patient or to you, sir.

Certainly, this is a pressing question. If, indeed, 53 percent of patients who had myocardial infarctions can be given a drug, fewer may die suddenly. These are burning issues that have to be solved, and cannot be solved in terms of planning on a year-to-year basis with inappropriate funding.

I am tempted to make the comparison of the President of the United States, or a Congressman, who has to run for election every second year. It is almost a similar analogy. You would be planning for your election, and not for the job that your constituents have elected you to do.

Finally, with regard to the question of funding. Dr. Austen, Dr. Corday, and Dr. Dreifus have made reference to the fact that this year only some 40 percent of the approved grants are going to be funded. If the administration's appropriation bill is accepted, there will be only 19 percent funded.

This has a great impact not only on the kind of research inroads that we are going to make but the support of a research cadre as well. Dr. Corday said in his travels he found that America leads the world in the conquest of disease. Well, America's lead in the conquest of disease depends on these young scientists who have ideas that are good enough to be approved by their peers; they must be funded so that they can pursue their research careers.

What happens if the young are not given the funds to pursue their ideas; there will be less investigative medicine. They will go into the practice of medicine, which is not too bad, but I think that you have to have a cadre of researchers and teachers, and academicians. If America is to maintain her lead in world medicine, as Dr. Corday described his findings, there has to be money appropriated.

I am not going to take more of your time except to say that I have submitted requested figures. Talking numbers in committees like this is somewhat dry, but I hope that you will think favorably and think humanly about the request of the NHLBI, both for your own constituents, for the American people and, indeed, for humanity.

Thank you, Mr. Chairman.

[Dr. Rosenfeld's prepared statement follows:]

STATEMENT OF
ISADORE ROSENFELD, M.D.
CLINICAL ASSOCIATE PROFESSOR OF MEDICINE
CORNELL UNIVERSITY MEDICAL COLLEGE
NEW YORK, NEW YORK

BEFORE
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE
REPRESENTATIVE PAUL G. ROGERS, CHAIRMAN

Mr. Chairman and Members of the Committee:

I am Dr. Isadore Rosenfeld, Associate Clinical Professor of Medicine, Cornell University Medical College. I am also engaged in the private practice of cardiology in New York City.

It is a pleasure and a welcome opportunity to be able to appear before this Committee again as a citizen witness for the National Heart, Lung, and Blood Institute, to support a three year reauthorization. As a practicing cardiologist, the diseases mandated to this Institute are of deep concern to me on a daily basis.

This year marks the thirtieth anniversary of the National Heart, Lung, and Blood Institute's existence as the Nation's focus for research on cardiovascular disease, and the fifth year since its authority was enlarged by Congress to advance the national attack on heart, blood vessel, lung, and blood diseases.

The enormity and significance of the responsibilities and the challenges placed before this Institute are readily appreciated when one considers the mortality, morbidity, and economic costs associated with these dreaded diseases. Heart disease has topped the list of the Nation's killers for several decades and remains so today in spite of the steady decline in death rates since 1950. In 1975, for example, cardiovascular diseases were responsible for more than one million deaths; just over three times those caused by cancer. In terms of morbidity, the toll is great, for example, an estimated 35 million Americans have hypertension, a major risk factor for heart disease and stroke. The economic costs of these diseases and the burdens are staggering. Diseases of the circulatory system alone cost the taxpayers of this country over 50 billion dollars.

But, the Institute has responded to this challenge and must continue to do so in an effective way. The Institute supports 20 large national program areas of which 10 are related to heart disease. These programs range from arteriosclerosis to circulatory assistance; major etiological processes to treatment. Because of the time constraints, I will limit my remarks to only a few examples on progress the Institute has made in hypertension and coronary heart disease.

In the area of hypertension, the Institute has made giant inroads. Hypertension mortality is down 80 percent since 1948, stroke mortality is down some 35 percent in the last thirty years, and the majority of this success has occurred in the last five years. The goals of the Institute, to reduce mortality in this disease, have been achieved, in large part, through the National High Blood Pressure Education Program. Through this program's activity, patient visits for high blood pressure diagnosis have increased substantially; over 50 percent since 197T. The Institute has also initiated several innovative and new programs. A new demonstration program to determine the effectiveness of statewide coordination of hypertension has been awarded to four states; a program to stimulate effective hypertension control in the work setting has been awarded; and a pilot training program for Blue Cross staff to develop methodologies and advise for employers who wish to establish employee health care programs in hypertension control is now underway. While the Institute develops these awareness and control programs, it also continues to look into the basic mechanisms responsible for the underlying causes of hypertension;

an area of biomedical research that is deserving of immediate and urgent attention if we will prevent or delay the progression of hypertension to its sequela of heart disease and sudden death. I have been most fortunate to serve on the Institute's High Blood Pressure Task Force over the last two years. This group has been defining the numerous basic and clinical opportunities and needs in high blood pressure.

Mr. Chairman, I am sorry to say that even though we can now treat hypertension effectively and prevent its sequela in over 90 percent of the cases, we still do not know its causes or the information essential for primary prevention. Such knowledge can only be realized through the acquisition of new knowledge through basic and clinical research.

My second area of interest is sudden death. As a member of the NHLBI supported US-USSR Working Group on Sudden Cardiac Death, I am well aware of the progress made internationally in this area.

It is reassuring to report that significant progress has been made in the understanding and treatment of coronary heart disease. The death rate has decreased some 18 percent since 1968. While the causes of this change are not well delineated, better techniques to recognize and manage the inhospital manifestations are important. Unfortunately, the majority of patients who die of myocardial infarction do so suddenly and about 60 percent do not live long enough to be admitted to the hospital.

The NHLBI is presently in the beginning stages of a clinical trial to test the efficacy of the prophylactic use of an antiarrhythmic drug, propranolol, to prevent the development of a fatal cardiac arrhythmia. The trial will involve some 4,200 patients who have had at least one heart attack and will require five years for patient recruitment, follow-up and analysis. This, however, is only one spot on the continuum of research which is ongoing and needed in this area. The clues that enable recognition of those patients at risk must be further defined. Many of the factors which convert chronic coronary heart disease into an acute catastrophic event must be elucidated. Further improvements in the management of the disease must be stressed. I urge that this Committee provide authorization levels which will help the Institute in effectively pursuing its important mandates.

As you may be aware, the appropriations to the Institute in recent years have been minimized by a low authorization ceiling. It might be pointed out that only 40 percent of the approved research grant application requests will be awarded this year and at the President's Budget level for fiscal year 1979 the percentage will drop to a mere 19 percent. This compares to 45 percent in 1976 and 61 percent in 1975. Last year, applications and approvals assigned to NHLBI escalated dramatically and the trend continues this year. It is of utmost importance that the renewal legislations provide authorization levels which will adequately enable the Institute to pursue an effective program.

A short-term renewal does not allow for the Institute's efforts to develop to a state at which meaningful observations and evaluation can take place. The stability of a three year authorization is necessary. The authorization levels I would like to recommend for this three year period are complementary to those which are recommended by the National Heart, Lung, and Blood Advisory Council; which are:

FY 1979	615.2 million	- of which $50 million would be used for prevention and control.
FY 1980	747.2 million	- of which $75 million would be used for prevention and control.
FY 1981	854.3 million	- of which $100 million would be used for prevention and control.

I see these figures as opportunity levels, levels which will provide for the opportunity to explore new leads while continuing current programs.

Mr. Chairman and distinguished members of this subcommittee, I wish to thank you again for letting me express my views on this extremely important topic. As a practicing physician, I am reminded everday of the advances that have been achieved through research which has been generously supported by this Committee and other members of Congress. We are now making major progress as is demonstrated by the striking decline in cardiovascular disease morbidity and mortality.

I urge the Committee to have the foresight to allow this excellent program to continue with adequate resources; to continue the job it has done so well over the past thirty years.

Mr. **Rogers**. Thank you very much, Dr. Rosenfeld, for a very helpful statement.

First of all, I think that the committee would like to say that certainly all of you, and the colleagues that you represent, and the American Heart Association as well, should take great pride in your accomplishments in reducing the death rate from heart disease by 13 percent. It is an amazing figure.

You should feel very pleased with what you have been doing, and what you have seen accomplished. The committee wants to publicly commend those who have been working in the heart field, in our institute, and in the research that has been done, and any application of our research effort, particularly in the field of hypertension where so much has been done.

We commend all of you and are grateful for what you have done for this country. Also, I want to recognize Dawn Bryan, who is the chief of public policy and government affairs for the American Heart Association, and the fine work she has done in relaying the concerns of the American Heart Association. Also, Mr. Mike Gorman, who has worked hard, and certainly has pointed out the problems of hypertension to this committee.

We want to express our thanks to you. We will certainly go over carefully the figures that you have raised, and give it our closest consideration.

Dr. Carter?

Mr. **Carter**. Thank you, Mr. Chairman.

I certainly concur with what you said. I think that great strides have been made, particularly since this legislation went into effect.

Dr. Rosenfeld, you have brought up the subject of sudden death. I notice that you have requested $25 million extra to be included for that. What do you think is the cause of these sudden deaths.

Dr. **Rosenfeld**. The evidence that we have is that electrical instability of the heart manifesting itself as a sudden lethal arrhythmia is the commonest mechanism of sudden death.

Now, what the factors are that cause this electrical instability are not clear. There are many theories that range from the influence of nervous activity, which would then require behavior modification, or neurological or pharmalogical control, as one mechanism. There may be biomedical or metabolic factors within the heart. There may be factors that interfere with coronary blood flow. These are all areas that are being looked into.

We can, for example, identify a certain number of individuals whom we can predict are candidates for sudden death. These are people who are at high risk by virtue of having had a heart attack some time in the past; or at high risk by virtue of having high blood pressure.

I am on the U.S. team that visits the Soviet Union in the scientific interchange between the two countries in the area of sudden death, and the Russians have found, in their data, that patients with untreated high blood pressure have a greater incidence of sudden death.

All of these factors include abnormal blood fats, and people who, if you monitor them with some of the newer devices that permit the rhythm to be analyzed over a 24-hour period, or a 36-hour period, you will find certain warnings, manifestations in the rhythm, which if you treat and suppress appropriately, may have an impact on sudden death.

Mr. **Corday.** I might answer that, too. The answer to your question, 50 percent of those who die suddenly have an impaired cardiocirculation. This was published in a special issue of the American Journal of Cardiology, which I edited May 26, 1977.

The psychic factors which cause sudden death are bad news. We both recognize that there are metabolic factors too. We have determined in dogs that when they have a coronary attack, just before they go into sudden death, a catastrophic disturbance in metabolism occurs, and that probably induces it.

Now our job is to try and see how we can affect this. How can we give the patient something ahead of time to prevent this from occurring.

Mr. Maguire brings up the question about jogging. Is it dangerous?

Patients who have had a previous coronary attack should not jog except in a gymnasium where there is an expert present that can defibrilate them back to life.

There is a study from the CAPRI program of Seattle funded by the NHLBI. Of the 850 people in the program who had had a previous coronary attack, 15 of them dropped dead while jogging in a gymnasium. However, because there was an attendant present, all 15 were defibrilated back to life.

There is another study reported in the Journal of the American Medical Association very recently about five cases of joggers who dropped dead, and all were defibrilated back to life.

So it might be that the people who had the previous coronary attack should only jog in a gymnasium where they can be defibrilated.

Mr. **Rogers.** I think that any information along those lines would be very helpful, we would make it part of the record. We will ask the National Institute also to comment. This is what we have asked for in our call for public information more particularly to stress the effects of exercise, nutrition.

We hope that we can accumulate some realistic evidence for the public, in the public information program.

Mr. Maguire?

Mr. **Maguire.** Thank you, Mr. Chairman.

One quick question. Dr. Austen, you say on page 1 of your statement that you attribute in large measure the dramatic reduction in heart disease to long-range commitment to the funding of basic research by the Congress. It is very nice to hear that.

I wonder, though, if you could comment as to whether there is any way to sort out whether one proportion of the reduction might be as a result of better preventive strategies, either individuals by themselves or their physicians, or what percentage might be the result of quicker reaction times, and better treatment once somebody is struck?

Dr. **Austen.** I don't think that I can answer your question completely, but I would like to try. What I would say is this. The things that we have been talking about and the things that we have been seeing really, in my view, would have to start somewhere.

You don't know about risk factors unless you have some knowledge. You have to start somewhere to get the knowledge. In a way, that is what I was referring to. You get fundamental knowledge so that you understand the problem. Then you use that knowledge, it seems to me, in a continuum, both in terms of therapy, and in terms of education.

That is how you end up with improvement in survival. I guess that I would only add, to continue to have the approval 5 years from now, so that we could be sitting here and not talking about the last 5 years being as good as the previous.

We need to continue to have both things going on. In no way did I mean to indicate that I do not absolutely, 100 percent, support prevention. I guess, what I would say is that both of them have to go hand in glove, and they really do so quite naturally, I think.

Mr. MAGUIRE. Thank you.

Mr. ROGERS. Thank you so much. We are grateful to have had you here.

There is a vote on the floor, and the subcommittee will stand in recess until 3:30.

[Brief recess.]

Mr. ROGERS. The subcommittee will come to order, please.

We have another distinguished panel with us this afternoon. The subcommittee wishes to express its appreciation for your presence, and making the effort to be here, to help us with the benefit of your thinking.

Thomas M. Fitzgerald, Cooley's Anemia Foundation; Dr. William S. Beck, American Society for Hemotology; and L. Jadwin Asfeld, president of the American Blood Commission.

We welcome each of you to the committee. Each of your statements will be made part of the record in full, and you may proceed as you desire.

Mr. CARTER. We are indeed grateful to Dr. Beck for his text. I believe you are the hematology department at Harvard Medical School, and a member of the American Society of Hematology.

Dr. BECK. Yes.

STATEMENTS OF L. JADWIN ASFELD, PRESIDENT, AMERICAN BLOOD COMMISSION; WILLIAM S. BECK, M.D., CHAIRMAN, PUBLIC INFORMATION COMMITTEE, AMERICAN SOCIETY FOR HEMATOLOGY; AND THOMAS FITZGERALD, MEMBER, BOARD OF DIRECTORS, COOLEY'S ANEMIA AND RESEARCH FOUNDATION FOR CHILDREN, INC.

Mr. ASFELD. Mr. Chairman, and Dr. Carter, it is certainly a pleasure to be here today. I do wish to call to your attention that the panelists who are with me officers of organizations that are also members of the American Blood Commission.

I am L. Jadwin Asfeld, this year's president of the American Blood Commission. The American Blood Commission welcomes this opportunity to express its strong support for the extention and increase of the authorization for the National Heart, Lung, and Blood Institute, as reflected in H.R. 10908 of the 95th Congress. [See p. 214.]

Public Law 94–278, passed in 1976, amended the Public Health Service Act, specifically designating the National Heart, Blood, and Lung Institute as the focal point for studies and research in the science and management of the Nation's blood supply.

Our support of the institute is based on the unique collaboration between the private and public sectors, which is also fostered by the National Heart, Lung, and Blood Institute.

The American Blood Commission was established in response to the widespread conclusions that the problems of blood collection and distribution in the United States could best be solved by bringing together many actively involved elements of the private sector, through an organization capable of coordinating the activities of blood services in this great Nation of ours.

In recognition of this problem, the Department of Health, Education, and Welfare announced a national blood policy in 1973. In summary, the basic aims of the policy were addressed to problems of safety, supply, quantity, and accessibility, and efficiency of the blood services of this country.

The policy called for the establishment of the American Blood Commission to coordinate the activities of the blood service facilities of this Nation, and to encourage and conduct research that would help to solve the problems in this field.

Among the expressed purposes of the National Blood Policy was the establishment of an all-volunteer blood donor system for the elimination of blood that was bought from paid donors.

The specialists have concluded that blood obtained from paid blood donors is more likely to be infected with undetectible hepatitis than is the blood from voluntary donors. After much discussion by interested parties, the American Blood Commission was founded and brought into existence in April of 1975.

Among the purposes of the commission are coordination of existing programs, and the development of new programs to improve blood services. A complete statement of its purposes can be found in the prepared statement.

The American Blood Commission is now in its third year as a recognized national agency for planning and coordinating the blood service system of this country. The 42 national organizations that comprise the commission are committed to full development of a total voluntary blood supply.

A list of the members of the commission appears as attachment 1 to the prepared statement. We are a private sector organization, working in a productive and, we believe, unique partnership with government and governmental agencies, such as the National Heart, Lung and Blood Institute.

To achieve the goals of the national blood policy, and to carry out the purposes of the American Blood Commission's task forces, expert individuals of all segments of our society have been included, including physicians, blood banking technologists, transfusion specialists, and trained nurses.

In addition to blood service professionals, these task forces include individual proficient in other health related professions and disciplines. The specific projects of the commission are described in more detail in our prepared statement.

Just to cite a few examples, the Commission with the financial assistance of the institute, has developed a uniform blood labeling system to replace the proliferation of hundreds of different practices that now exist, and has presented its recommendations to the Food and Drug Administration.

The American Blood Commission is also developing a national blood data center that will, for the first time in the history of this country, provide an accurate data base for planning, managing and evaluating blood services.

Because of the importance of cost effectiveness, the American Blood Commission is aggressively developing a system of coordinating blood services and resources on a regional basis throughout this country.

The American Blood Commission also undertakes other research information and educational programs. These various programs have been supported by grants from several private foundations, and by six contracts with the National Heart, Lung and Blood Institute.

Representatives of conflicting viewpoints over the philosophy and technique of blood donors are represented in the membership of the American Blood Commission. It has been one of the principal functions and purposes of the American Blood Commission to find the means of reconciling these different positions.

Established in 1975, the American Blood Commission is a nonprofit organization incorporated under the laws of the District of Columbia. To strengthen the commission, a Federal charter is now being sought because it would reflect an endorsement of its purposes by the Congress of the United States.

We are implementing the goals of the National Blood Policy by improving and coordinating blood collecting systems in order to assure a safe and adequate supply of voluntary donated blood for the Nation.

The commission's effectiveness is based on the continued development of a consensus, and its increased influence in policy formulation and program development. These activities are undertaken by a broadly based membership, representative of donors, patients, and health care professionals. Strengthening the American Blood Commission is the best assurance that its goals will be achieved, and that the differences in the blood banking community will ultimately be reconciled in a logical way that will best serve the national resource.

Thank you, Mr. Chairman.

[Testimony resumes on p. 224.]

[Mr. Asfeld's prepared statement and attachment follow:]

American Blood Commission
1901 North Ft. Myer Drive, Suite 300
Arlington, Va. 22209
(703) 522-8414

March 1, 1978

STATEMENT ON BEHALF OF

THE AMERICAN BLOOD COMMISSION

ON H. R. 10908

I am L. Jadwin Asfeld, this year's President of the American Blood Commission.

The American Blood Commission welcomes this opportunity to express its strong support for the extension and increase of the authorization for the National Heart, Lung and Blood Institute, as reflected in H.R. 10908 of the 95th Congress.

When the President signed Public Law 94-278, in 1976, amending the Public Health Service Act, which extended the authority of the National Heart, Blood Vessel, Lung and Blood Act of 1972 for two fiscal years there were two basic substantive changes that affected blood resources. The principal change involved a series of amendments designed to provide increased emphasis on programs in blood research and in the management of our blood resource. The 1976 Act legislated a change in the name of the National Heart and Lung Institute to the "National Heart, Lung and Blood Institute" and made a comparable change in the name of the Institute's Advisory Council. Thus, this legislation specifically designated the National Heart, Lung and Blood Institute as the focal point for studies and research into the science and management of the Nation's blood resource.

Some of the American Blood Commission's activities fall outside the scope of fundamental biomedical research; they are more appropriately defined within the development of the nation's blood resources. Still, we heartily endorse the continuation of the NHLBI. Our support of the Institute is based on the unique collaboration between the private and public sectors which is fostered by the National Heart, Lung, and Blood Institute.

The American Blood Commission was established in response to a widespread conclusion that the problems of blood collection and distribution in the United States could best be solved by bringing together many actively involved elements of the private sector through an organization capable of coordinating the activities of "the pluralistic system of blood services in the the nation." A list of members is attached.

The generally recognized problems in the collection and distribution of blood for health care were: Dangerous shortages of supplies of blood have appeared in various parts of the country from time to time.

Despite recurring regional shortages of blood, excessive quantities of blood have been wasted by expiration of their useful life on the shelves of blood service facilities in places where the demand for particular types of blood did not meet the supply.

Lives of patients have been jeopardized when blood of an improper type or blood from a donor infected with certain diseases is transfused. In particular, because of the practical impossibility at the present time of identifying blood infected with certain types of hepatitis, it is essential to avoid, by all reasonable means, the collection of blood from persons infected with that disease.

The system of charging for blood transfusions has varied greatly throughout the nation, causing some patients to pay far more than others.

Some doctors may be using whole blood for transfusions under circumstances when fractionation into components of blood would be a more appropriate method of transfusion therapy and more satisfactory in the management of the blood resources of the nation.

In recognition of these problems the Department of Health, Education and Welfare, announced the National Blood Policy in July 1973. In summary, the basic aims of the Policy were addressed to problems of safety, supply, quantity, accessibility, and efficiency in the blood services of the country. The policy called for the establishment of the American Blood Commission to coordinate the activities of the blood service facilities of the nation and to encourage and conduct research that would help to solve the problems in the field. Among the expressed purposes of the National Blood Policy, was the establishment of an all voluntary blood donor system through the elimination of blood obtained from paid donors. Many specialists have concluded that paid donors are more likely to be infected with undetectable hepatitis than is blood from voluntary donors.

In response to a proposal of the Department of Health, Education and Welfare, a group of organizations in the private sector, concerned with blood supplies from various points of view, organized an Ad Hoc Committee to establish the American Blood Commission. The Ad Hoc Committee met many times in 1974 and 1975, and in April, 1975, the American Blood Commission formally was brought into existence by those organizations.

The purposes of the American Blood Commission are stated clearly in Article I of its bylaws to include:

- developing a quality national blood program accessible to all;
- developing increased public understanding of the role of and necessity for blood;
- coordinating functions of its members relevant to blood services;
- examining arrangements for the interchange of blood and the management of inventories and recommending improvements;
- encouraging the development of improved technical standards and regulations;
- encouraging the collaboration of agencies of government and the private sector in accrediting and inspecting blood service facilities;
- promoting the improvement of the competence of personnel engaged in providing blood services;
- developing a national system for the collection and analysis of data;
- studying existing techniques and accounting practices;
- stimulating research into donor recruitment;
- developing a resource center to serve all who seek understanding of blood banking and blood services and to function as a channel of information between the private sector and government.

To achieve the goals of the National Blood Policy and to carry out the purposes of the American Blood Commission, Task Forces of experienced individuals from all segments of our society have been created, including physicians, blood banking technologists, transfusion specialists and trained nurses. In addition to these blood service professionals the Task Forces include individuals proficient in other health related professions and disciplines.

Task Force recommendations are presented to the Board of Directors and to the members of the Commission for their review and consideration.

The following is a list of the specific projects and studies undertaken since the inception of the Commission:

The Task Force on Regional Association of Blood Service Units has developed guidelines and criteria to assist in the regionalization of local programs of blood services in order to improve the effectiveness of blood services in geographically integrated areas. Regional resource-sharing will improve inventory control, guarantee that the needs of all patients are being met, and lend greater cost-efficiency to the provision of services.

The Task Force on a National Blood Data Center has found that accurate and reliable data on the operation of the nation's blood service system have never been systematically compiled. The Task Force is now developing a national user-oriented Data Center that will provide comprehensive data and analysis and evaluation services.

The Committee on Utilization of Blood and Blood Components will support scientific and educational programs among teaching institutions and the medical professions with the goal of efficient utilization and conserving the total blood supply, and of the greater safety of patients receiving transfusions.

The Task Force on Donor Recruitment, sponsored by the ABC, has completed research on blood procurement practices which has yielded comparative information about donor recruitment strategies and costs.

The Committee on Commonality in Blood Banking Automation within the American Blood Commission has designed a uniform blood bag labeling system which will replace the proliferation of labeling practices now in use. When introduced for general application, the uniform labels, which contain "bar codes" and are readable both by eye and machine, are expected to eliminate costly, confusing, and potentially tragic errors in labeling blood and recording testing results. They will also facilitate gradual introduction of automated systems according to local needs.

In addition to its Task Forces and Committees, the ABC undertakes other research, informational and educational programs. These programs have been supported by grants from several private foundations and by six contracts with the National Heart, Lung, and Blood Institute.

The governing body of the American Blood Commission is a Board of Directors consisting of representatives of 28 member organizations. The Board has met quarterly since the American Blood Commission was established and its members have actively participated in both Board and Committee meetings. The two largest organizations concerned with blood provision, the American Association of Blood Banks and the American National Red Cross, each have two members serving on the Board The 28 other organizations are allotted one vote each. The thirty-first member of the Board serves in an "at-large" capacity; this position is currently occupied by the Commission President.

An Executive Committee serves in an advisory capacity to the Board and aids in facilitating the progress of the American Blood Commission.

For many years the people engaged in blood banking have been divided by serious differences over the philosophy and technique of donor recruitment. One such issue has been whether payment of cash to blood donors should be continued. Those opposed to such payments have maintained that it is both unethical to deal in human tissues on a commerical basis and that cash payment encourages donation by unhealthy persons which in turn entails added risks of injury by contaminated blood. On the other side has been the argument that the increased risk is slight and is fully justified because it is a good way to assure adequate supplies of blood and blood components.

A second issue is between those who believe that the donation of blood is a "community responsibility." This philosophy calls for all healthy citizens to contribute to a blood supply that must be maintained for those in need. On the other hand many believe that the maintenance of blood supplies is an "individual responsibility" that calls for every person who receives blood to accept responsibility to "replace" those units through donations by the user or by the patient's relatives or friends, or to pay a non-replacement fee in lieu of replacement.

Representatives of these viewpoints are represented in the membership of the American Blood Commission. It has been one of the principal purposes and functions of the ABC to find a means of reconciling these differing positions.

The American Blood Commission was established in 1975 as a non-profit organization under the laws of the District of Columbia. In order to strengthen the Commission, a Federal charter is now being sought, because it would reflect an endorsement of its purposes by the Congress of the United States.

The American Blood Commission is achieving the goals of the National Blood Policy by improving and coordinating blood collection systems in order to assure a safe, adequate supply of voluntarily donated blood for the nation. The Commission's effectiveness is based on the continued development of a consensus and its increasing influence, in policy formulation and program development. These are undertaken by a broadly based membership representative of donors, patients and health care professionals. Strengthening the American Blood Commission is the best assurance that its goals will be achieved, and that the differences in the blood banking community will ultimately be reconciled in a logical way that will best serve the national interest.

# # #

Attachment I

American Blood Commission

Members

American Association of Blood Banks
American Association of Clinical Histocompatibility Testing
American Association of Tissue Banks
American Association of Trauma Specialists
American Cancer Society
American College of Emergency Physicians
American College of Physicians
American College of Surgeons
American Federation of Labor - Congress of Industrial Organizations (AFL-CIO)
American Heart Association
American Hospital Association
American Legion
American Medical Association
American National Red Cross
American Nurses' Association
American Osteopathic Association
American Osteopathic College of Pathologists, Inc.
American Society for Medical Technology
American Society of Anesthesiologists
American Society of Clinical Pathologists
American Society of Hematology
American Surgical Association
Assocation of American Cancer Institutes
Blue Cross Association
Catholic Hospital Association
College of American Patholgists
Communications Workers of America
Cooley's Anemia Foundation
Council of Community Blood Centers
International Union, United Automobile and Agricultural Workers of America (UAW)
Leukemia Society of America
National Association of Manufacturers
National Association of Patients on Hemodialysis and Transplantation, Inc.
National Association for Sickle Cell Disease, Inc.
National Hemophilia Foundation
National Kidney Foundation
National Medical Association
National Retired Teachers Association - American Association of Retired Persons
Pharmaceutical Manufacturers Association
Society for Cryobiology
United Way of America
Veterans Administration

Mr. ROGERS. Thank you very much for your statement.

We have a vote on the floor. We apologize to the witnesses, but if you will bear with us, we will try to vote and come back immediately.

The subcommittee will stand in recess for 10 minutes.

[Brief recess.]

Mr. ROGERS. The subcommittee will come to order.

We will continue with our hearing.

Dr. Beck, you may proceed in any way you like.

STATEMENT OF WILLIAM S. BECK, M.D.

Dr. BECK. Chairman Rogers and members of the subcommittee: Thank you for allowing me to testify before you on behalf of the American Society of Hematology in connection with the renewal of the National Heart, Lung, and Blood Act. For hematologists and, indeed, for the Nation, this is an important occasion.

I am Dr. William S. Beck. I am director of hematology research at the Massachusetts General Hospital, in Boston, and a professor at Harvard Medical School. I am also chairman of the Public Information Committee of the American Society of Hematology, which is the hematology community's instrument for informing the public and its representatives in government of the needs and high promise of our particular branch of biomedicine.

I had planned to tell you a little bit about what hematology is, but I think that we all know very well that it has to do with blood and blood diseases. This includes the various disorders of bleeding and clotting, such as thrombosis and hemophilia; genetic diseases such as sickle cell anemia, and thalassemia, and so on, and also blood transfusions.

I know that the time is short, and I will make my points just as briefly as I can [see p. 226].

First, I want to acknowledge and tell you how pleased we are about the decision of the subcommittee and the Congress to add to the name of a great institute the word "blood." This is a very happy event for those of us in this field.

Hematology does reach back into antiquity, and yet it stands today at the cutting edge of basic biological science. It is a field with more than its share of Nobel Prize winners, and its findings impinge on all of the biological sciences—molecular biology, genetics, immunology, and biochemistry—and they reach as well into every corner of clinical medicine and surgery. We are proud of our field, and of the institute's new name.

Second, I wish, on behalf of the Nation's hematologists, to thank you, Mr. Chairman, for your foresight in proposing the 3-year renewal of this legislation. This provides the degree of stability that all of us feel is essential for wise and effective utilization of our resources and for the intelligent exploitation of our creative impulses. I cannot say enough in praise of your thinking in this matter.

Third, I should like to mention in a few sentences some of the recent achievements of hematology and some of its future opportunities. I have gone into this at some length in my statement.

I just want to say that I think the field is bursting with new developments, each one of which poses some important challenges to the future. Maybe I could mention just one as an example.

A new methodology of transfusing white blood cells is a very important development that adds some new dimension to the treatment of leukemia, cancer and overwhelming infection. But great unsolved problems arise about possible unknown effects on those who donate white cells by the procedure called leukopheresis. I know that the Blood Division of NHLBI urgently wants to investigate these questions and develop procedural guidelines.

I can go down the list, and tell you about new things, such as clotting and thrombosis, hemophilia, work on anticoagulants, sickle cell anemia, von Willebrand's disease—which is like hemophilia, but which is not hemophelia—and so on. At last we are turning the field of blood transfusion into a science. Finally, the exciting new work with blood substitutes should be mentioned.

Many things are happening, and I want you to know about them, and to share a little of the excitement we feel as we move ahead.

We have received a high appropriation this year, but nevertheless, because of the increased number of grants submitted, we were only able to fund 45 percent of approved grants, and this is to be compared with the more traditional level of 60 percent.

Thus, the pool of noncommitted funds has shrunk. The director is operating with about $50 million less this year in uncommitted funds than he had in the last 2 years. We hope that we can do better in the next 3 years.

We are recommending for the next 3 years totals of $600, $690, and $795 million, respectively. Of these sums, $35, $40, and $45 million would go to the institute's excellent prevention and control programs.

We are also concerned that research training programs be adequately funded. It is difficult to make specific recommendations in this area. I sincerely hope that in fiscal year 1979, at least $25 million will be available to the institute for its training programs.

In summary, we wish to praise the subcommittee for its foresight in providing the stability of a 3-year bill. But we urgently appeal for authorization or opportunity levels that would allow us to make the most of this welcome period of stability.

We especially emphasize the importance of allowing the institute director to explore new initiatives and promising new programs as well as provide continuing funding for present programs.

Especially is this true in the blood field which is bursting with new and exciting opportunities and prospects. In view of current inflationary trends, we note that a 3-year bill fixes authorizations for 3 years. We would not wish to be trapped in an unrealistic or inadequate set of projections.

Finally, I would like to compliment you, Mr. Chairman, and Dr. Carter, for your ongoing dedication to the field of biomedical research, both in its basic and applied forms and for your leadership and understanding.

We who do this work are deeply encouraged by the feeling we have that you hear us and that you agree with us on the importance to our Nation of a sound and balanced research effort.

Thank you.

[Testimony resumes on p. 234.]

[Dr. Beck's prepared statement and attachment follow:]

TESTIMONY

OF

WILLIAM S. BECK, M.D.

CHAIRMAN, PUBLIC INFORMATION COMMITTEE,

AMERICAN SOCIETY OF HEMATOLOGY

AND

ASSOCIATE PROFESSOR OF MEDICINE, HARVARD MEDICAL SCHOOL

AND

DIRECTOR, HEMATOLOGY RESEARCH LABORATORY, MASSACHUSETTS GENERAL HOSPITAL

BOSTON, MASSACHUSETTS

MARCH 1, 1978

BEFORE THE

SUBCOMMITTEE ON HEALTH AND ENVIRONMENT

U.S. HOUSE OF REPRESENTATIVES

WASHINGTON, D.C.

Submitted testimony

Summary fact sheet on page 1

March 1, 1978

Summary Fact Sheet

1. **Definition of hematology**

Hematology, the science of blood, is concerned with research on blood and blood diseases and with care of patients with various blood diseases--among them, bleeding disorders such as hemophilia; clotting and its disorders, especially thrombosis; genetic diseases such as sickle cell anemia and thalassemia (Cooley's anemia); nutritional anemias, and leukemias. It is also concerned with the theory and practice of blood transfusion and with the procurement and handling of blood and blood products.

2. **Hematology support at NHLBI in FY 78**

	In millions
Total NHLBI authorization	456.3
Total NHLBI appropriation	445.6
Amount allocated to Division of Blood Diseases & Resources	61.5

3. **Recommended authorization levels for next three years**

Year	Authorization levels for prevention and control programs [Section 414(b)]	Authorization levels for research and "other purposes of Act" [Section 419B]	Authorization levels (total)
		in millions	
FY 79	35.0	565.0	600.0
FY 80	40.0	650.0	690.0
FY 81	45.0	750.0	795.0

Dr. William S. Beck
Chairman, Public Information Committee,
American Society of Hematology

Mailing address:

Massachusetts General Hospital
Boston, Massachusetts 02114
Phone: 617/726-3760

Chairman Rogers and Members of the Subcommittee:

Thank you for allowing me to testify before you on behalf of the American Society of Hematology in connection with the renewal of the National Heart, Lung and Blood Act. For hematologists and for the nation this is an important occasion.

I am Dr. William S. Beck. I am director of hematology research at the Massachusetts General Hospital in Boston and a professor at Harvard Medical School. I am also chairman of the Public Information Committee of the American Society of Hematology, which is the hematology community's instrument for informing the public and its representatives in government of the needs and high promise of our particular branch of biomedicine. The Society for which I speak is the national organization of hematologists. Hematologists, of course, are concerned with blood--with research on the scientific problems of blood and blood diseases and with the care with patients with blood diseases. These include the various disorders of bleeding and clotting, such as thrombosis and hemophilia (a diverse collection of common and rare afflictions); genetic diseases, such as sickle cell anemia and thalassemia (or Cooley's anemia); the nutritional anemias, leukemias, and so on. Significantly, many forms of anemia are secondary to primary diseases elsewhere in the body—cancer, uremia, etc. Some of these conditions result in heavy demands for transfusions of blood and blood products. We are also interested in this whole area.

* * *

I am aware that time is short. Let me then recite my few points in summary fashion. There are four.

1. First, I want to say how pleased and proud American hematologists are at the decision of this Subcommittee and the Congress to add "Blood" to the name of a great Institute. This was a happy event for those of us who work at hema-

tology, a branch of medicine and biological science which we would like to feel has unusual distinction. Though it reaches back into antiquity, hematology stands today at the cutting edge of basic biological science. It is a field with more than its share of Nobel Prize winners and its findings impinge on all of the biological sciences--molecular biology, genetics, immunology, and biochemistry--and they reach as well into every corner of clinical medicine and surgery. We are proud of our field and of the Institute's new name.

* *

2. Second, I wish on behalf of the nation's hematologists to thank you and to congratulate you, Mr. Chairman, on your wisdom and foresight in proposing that the renewal legislation for this Institute be in the form of a three year bill. This provides a degree of stability that all of us feel is absolutely essential for the wise and effective utilization of our resources and for the intelligent exploitation of our creative impulses. I cannot say enough in praise of your thinking in this matter.

* *

3. Third, I should like to mention in a few sentences what cannot be adequately compressed into a few sentences--some of the recent achievements in the field of hematology and some of the opportunities and challenges that face us in the future. I wish I could communicate to you the feelings I have of excitement and gratification about what is going on in this field today, much of it under the stimulus and support of the National Heart, Lung and Blood Institute. I have recently returned from the San Diego meeting of the American Society of Hematology, where I listened for several days to summaries of new work. The field is bursting with developments and each development poses new challenges. I can mention only a few, but each is a vital element of the NHLBI program.

a. New methods of transfusing white cells (granulocytes), an extraordinary development that adds an important new dimension to the treatment of leukemia, cancer and overwhelming infection. But great unsolved problems arise about possible unknown effects on those who donate white cells by the procedure called leukopheresis. The Blood Division of NHLBI urgently plans to investigate these questions and develop procedural guidelines.

b. New developments in the field of clotting and thrombosis, among them new findings on the chemistry of the blood platelet, which undoubtedly give it a role in the generation of the dreaded and unwanted clot we call thrombosis. Significantly, these data suggest new ways of interfering with this process and we want to work them out. NHLBI hopes soon to isolate and characterize factor VIII, the clotting factor missing in hemophilia, and develop better concentrates of factors VIII and IX. In this way we are taming the dread disease hemophilia. As for thrombosis, efforts are planned to improve our ability to detect the earlier stages of thrombosis, to detect individuals of risk, and to evaluate newer prophylactic and therapeutic agents such as the anti-platelet drugs just mentioned.

c. New basic discoveries about the way anticoagulants act, especially the anticoagulant known as heparin. These give future promise of entirely new insights into the reasons why blood does not normally clot within the body. This work promises to become a major breakthrough.

d. New work on the hormone erythropoietin, which is the body's messenger for calling forth new red cell production. The Institute hopes to study purified erythropoietin to hasten the day when it can serve as a therapeutic agent for anemia.

e. Exciting data on the nature of sickle cell anemia and the molecular basis of sickling and especially of new agents and factors that might inhibit sickling within the red cell and within the patient. These give promise of future progress in the treatment of sickle cell disease. It is planned also to improve the diagnosis of sickle cell trait and better sickle cell counselling programs on the psychosocial aspects of this condition.

f. New insights into that bizarre condition called von Willebrand's disease, which is like hemophilia but is not hemophilia. Study of von Willebrand's disease (such as one planned on occlusive disease in this condition) promises to open new horizons in the understanding of blood clotting.

g. Important new techniques for the management of blood transfusion that promise (1) to revolutionize present methodology, which is unnecessarily costly and complex, and (2) to turn the field of blood transfusion at last into a science. The Institute plans in future to develop blood substitutes to relieve the stress on national blood resources and to avoid many of the undesirable side effects of blood transfusions. It also hopes to improve the methodology for collection and transfusion of platelets.

h. Finally, we heard about those fascinating vitamins, folic acid and vitamin B_{12} that are necessary for the production of red blood cells and are such a source of pride to Bostonians, since much of the work that led to their discovery was done in Boston.

All of these new discoveries have crowded in on me in recent days as I prepare to teach a spring hematology course to my Harvard medical students. I know of no field that places such extraordinary demands on the professor or textbook writer who seeks to keep his story up to date. New things are happening that are promising and important. I simply want you to know about them and to share with me a little of the feeling of excitement we all have as we look to the future.

* *

4. My fourth and final point has to do with projected authorization levels.

My colleagues in the field of hematology realize that authorization levels are opportunity levels. We are deeply concerned at the sharp decrease in the number of dollars available to the Institute director for new commitments this year. Although NHLBI received an increase in its appropriation last year it was able because of the increase in the number of grants submitted and approved to pay only 45% of them. This is to be compared with a traditional average percentage between 1970 and 1976 of 60%. Moreover, the Institute's present commitments total about $418 million. With an appropriation this year of $454.4 this leaves only about $36 million in non-committed funds under circumstances that would require $90 million to restore the funding level even to 50% and to take care of important new initiatives. They are therefore about $54 million short and are operating at a level of non-committed funds that is about $45 million below the level that prevailed in the last two years. We must do better than that and we are recommending totals for the three years of $600, 690, and 795 million, respectively. Of these sums, $35, 40, and 45 would go to the Institute's excellent prevention and control programs. We are also concerned that research training programs be adequately funded. It is difficult to make specific recommendations in this area. I sincerely hope that in FY 79 at least $25.0 million will be available to NHLBI for its training programs.

These totals, we feel, should provide needed opportunities and should be more compatible with the state of the economy and the increasing tempo of research in this critically important field.

* * *

In summary, we wish to praise the Subcommittee for its foresight in providing the stability of a three-year bill but we urgently appeal for authorization or opportunity levels that would allow us to make the most of this welcome period of stability. We especially emphasize the importance of allowing the Institute director to explore new initiatives and promising new programs as well as provide continuing funding for present programs. Especially is this true in the blood field which is bursting with new and exciting opportunities and prospects. In view of current inflationary trends, we note the fact that a three year bill is fixed for three years. We would not wish to be trapped in an unrealistic or inadequate set of projections.

Finally, I would like to compliment you, Mr. Chairman, and the Subcommittee for your ongoing dedication to the field of biomedical research, both in its basic and applied forms and for your leadership and understanding. We who do this work are deeply encouraged by the feeling we have that you hear us and that you agree with us on the importance to our nation of a sound and balanced research effort.

Mr. ROGERS. Thank you very much, Dr. Beck, for an excellent statement. We would also like to note that John Grapenhoff has been most helpful to the committee in getting information for us.

Next, I believe, is Mr. Fitzgerald.

STATEMENT OF THOMAS M. FITZGERALD

Mr. FITZGERALD. Thank you, Mr. Chairman, and Dr. Carter.

I am here today on behalf of the Cooley's Anemia Foundation. I am a member of the board of directors, and on behalf of the foundation, I want to thank you for permitting us to come and testify here today, about our interest in the Heart, Lung, and Blood Institute.

Our recommendations regarding renewal are very specific, and they are two.

First: We believe that funding for this program, at least for the first year, should be at least $600 million. We concur with Dr. Beck's recommendation for the field of hematology, and this field would be inclusive of the training programs.

We are convinced by the study of the situation that these funds are required. Since the addition of the word "blood" to the title of the Institute, there has been considerable movement forward in that field, but the opportunities for advances in research have not been supported by increases in funding.

Second; we believe that the bill should renew the life of the Institute and its programs for a period of 3 years. We concur with your recommendation that this be done.

The physicians on our own medical advisory committee know the seriousness of the problem that would be created with only a 1-year renewal. Simply put, neither the Institute nor the researchers in the blood field would be able to plan adequately on a 1-year renewal.

As you know, there is now a task force of the Heart, Lung, and Blood Institute reviewing every aspect of research and care for Cooley's anemia. Preliminary reports are now being developed, but we do know that there will be a great need for research funds as well as a program of stable, long-term planning in order for the opportunity for research advances to be pursued.

We would like to take a few moments to provide this committee with some background information about the disease known as Cooley's anemia.

Cooley's anemia is the name used to describe a very severe form of a hereditary blood disease. This disorder occurs most commonly in individuals whose ancestors are natives of the countries surrounding the Mediterranean Sea. This disease is also called Mediterranean anemia, or thalassemia.

Thalassemia major, the more sever form of the disease, occurs in children born to parents who both carry the trait. Because individuals with the trait, or the minor form of the disease, are not in any significant way handicapped physically, it is of great importance to distinguish between thalassemia major and thalassemia minor.

Individuals who have thalassemia minor have a normal lifespan, and enjoy normal health. Whereas, the individuals with thalassemia major succumb to the disease. Thalassemia minor, the trait never increases in severity or converts to the severe form of the disease.

Thalassemia major usually becomes manifest during the first year of life, and both sexes are equally affected. There are several manifestations of the anemia. For example, there is a reduction in the rate at which red blood cells are formed in the marrow of the bone and released into the blood stream. Those cells that are produced are defective, and they cannot survive more than half the life span of normal red blood cells.

As a result of the chronic state of anemia, the children with this disease are greatly handicapped. Bone growth is poor. They are usually small for their age. Because of the abnormalities of the bone marrow, there are alterations in the skull and other bones, so that there is a characteristic facial expression found, which gives many of the children the appearance of being related.

The bones are more fragile than normal, and fractures occur almost spontaneously.

At present, the only known effective treatment for Cooley's anemia is the administration of blood transfusions to alleviate the constantly occurring anemia. Blood transfusions may be required as often as once a week. There is no known cure.

I would like to call this committee's attention to the fact that Cooley's anemia is a serious disease. It is fatal to our children. It works incredible emotional and economic hardships on their family. It puts a serious strain on the blood distribution network of our country.

As I have said, this foundation has tried to bring to the public's attention the seriousness of this disease, but very little is known about the disease. Progress has been very slow.

There have been some recent successes particularly in the prevention of the accumulation of iron in the organs of the child's body, a so-called iron chelating agent which has recently been cleared for use by the Food and Drug Administration.

The accumulation of iron in the organs is caused by the constant transfusions that are required and as more and more transfusions must take place, the body is unable to rid itself of the iron, which is continually deposited in the organs.

The chelating agent chemically removes some of this iron, thus lessening the effect of the buildup. However, this is only a sometimes effective agent to control the side effects of the transfusion and does nothing to control the disease itself.

I wish to thank you for the opportunity to address the committee.

[Testimony resumes on p. 241.]

[Mr. Fitzgerald's prepared statement follows:]

TESTIMONY

OF

COOLEY'S ANEMIA BLOOD AND RESEARCH FOUNDATION FOR CHILDREN, INC.

420 Lexington Avenue
N.Y., N.Y. 10017

BY

THOMAS M. FITZGERALD, ESQ.

Before the Subcommittee on Health & Environment

U.S. House of Representatives

March 1, 1978

Mr. Chairman, I am Thomas M. Fitzgerald, an attorney, and a member of the legislative committee of the Cooley's Anemia Blood and Research Foundation for Children, Inc. We deeply appreciate the opportunity to testify before you regarding the renewal of the Heart, Lung and Blood Act.

Our recommendations regarding renewal are very specific:

First, we believe that the funding for the program, for the first year of this new law, should be at least $600 million, inclusive of training programs. We are convinced by the study of the situation, that these funds are required. Since the addition of the word "blood" to the title of the Institute, there has been considerable movement forward in that field, but the opportunities for advances in research have not been supported by increases of funding.

Second, we believe that the bill should renew the life of the Institute and its programs for a period of three years. Last year, because of a number of reasons, including the necessity of a new Administration to study the program, the Institute's programs were renewed for one year. As you know the Senate bill suggests another one year renewal, while you indicate a three year bill would be reasonable.

We agree with you. The physicians on our own medical advisory committee know how serious the problem would be if there is only a one year renewal--simply put, the Institute cannot plan well, and neither can researchers in the blood field.

As you may know, there is now a task force of the Heart, Lung and Blood Institute reviewing every aspect of research and care regarding Cooley's Anemia. Preliminary reports are now being developed. We know that there will be a great need for research funds, as well as a program of stable, long-term planning, in order that the opportunities for research advances can be pursued.

I think that this committee would find some background information on the disease known as Cooley's Anemia useful.

Cooley's Anemia is the name commonly used to describe the severe form of a hereditary disease of the blood. It was Dr. Thomas B. Cooley, an American physician, who described this as a separate and specific type of blood disease about 1925.

This disorder occurs most commonly in individuals whose ancestors were natives of the countries surrounding the Mediterranean Sea. In the United States patients are of Italian, Greek, Turkish, Southern France, North African, Chinese, Spanish, Irish and Israeli descent.

The disease, also called Mediterranean Anemia or Thalassemia, is inherited according to Mendelian laws and it is known that the severe form (Thalassemia Major) occurs in a child born of parents both of whom must be carriers of the trait. According to this accepted concept, approximately one quarter of all children born of marriages of two individuals with the trait, will have the severe form of the diseases. Another twenty-five per cent of the offspring will be perfectly normal, and fifty per cent will be carriers themselves. Any such hereditary situation, of course, is valid in a statistical sense only, and may not be referable to one family where instances are known of only one affected (anemic) child out of ten, or the reverse, where three out of three children may be affected.

Because individuals with the trait or minor form of the disease are not in any significant way handicapped physically, and in whom the only manifestation may be detectable changes in the size and shape of the red blood cells, it is of great importance to distinguish between Thalassemia major and Thalassemia minor. Individuals with Thalassemia minor have a normal life span and enjoy normal health, whereas individuals with Thalassemia major may succumb to the disease in a matter of one or two decades. The trait never increases in severity or converts to the severe form of Cooley's Anemia.

Thalassemia major usually becomes manifest during the first year of life. Both sexes are equally affected. The earliest signs may be pallor, listlessness, loss of appetite, and irritability. Examination of the patient, by a physician, usually reveals an enlargement of the spleen and liver to some degree, pallor of the skin and mucous membranes, and sometimes a slight degree jaundice (yellow coloration) of the whites of the eyes. Blood examination will usually show typical changes in the shape, numbers of the erythrocytes (red blood cells), and a variety of alterations from the normal in special properties of the blood cells, in addition to a severe anemia.

There are probably several defects which lead to the anemia. For example, there undoubtedly is a reduction in the rate at which red blood cells are formed in the marrow and released to the blood vessels. Those cells that are produced are defective in that they do not survive in the blood vessels for more than 1/3 to 1/2 of the normal life span of red cells, which should be about 90 to 120 days. There are complications which develop in certain individuals which further reduce the rate of blood cell production and survival time of the formed cells. In these patients the greatly enlarged spleen may be the cause of this additional hindrance.

As a result of the chronic state of anemia the children with this disease are greatly handicapped. Bone growth is poor - they are therefore usually small for their age. Because of abnormalities of the bone marrow there are alterations of the skull and other bones, so that a characteristic facial expression is found, which give many of these children the appearance of being related. The bones are more fragile than normal, and fractures occuring almost spontaneously are quite common. The anemia causes easy fatigability, and a lack of pep and energy. Frequent nose bleeds is a common finding in many patients. When anemia is severe, low grade fever may be noted. There is no particular increase in susceptibility to infections.

At present the only effective treatment is the proper administration of blood transfusions to alleviate the constantly recurring anemia. There are other specific treatments for various complications of the basic disease.

There seems to be a continuous spectrum in the degree of severity of the disease from those children who require blood transfusions as often as once a week to those who rarely need transfusions. Some children die within a few years and others are known who are alive in their twenties. There is no known cure.

I would like to call to the panel's attention that this is a very serious disease. It is fatal to our children, it works incredible emotional and economic hardship on families, it puts serious strains on the blood distribution network of the country.

And yet as I have said, this Foundation has attempted to bring to the public attention the seriousness of this disease, and until now the federal government has done very little in the way of attempting to help solve the problem. After all this time, very little is known about the disease. The researchers know little, and because of limitations in funds for research, progress in this area is very slow. There have been some recent small successes, including a recent movement forward in the field of helping to prevent the accumulation of iron in the organs of the child's body; a so-called iron chelating agent has recently been cleared for use by the FDA. The accumulation of iron in the orgnas of the body is caused by the constant transfusions that are required and as more and more transfusions must take place, and the ever [illegible] deposited in the organs. Thus the chelating agent, chemically, removes some of this iron, thus lessening the effects of the buildup. However, this is only a sometimes-effective agent to control a side effect of transfusion, and does nothing to control the disease itself.

The scientists know that there are only a few leads, and lack of funding for research in this field, and in the genetic blood disease field in general, prevents scientists from moving forward rapidly on this and other diseases.

Thank you for the opportunity to testify, Mr. Chairman. I would be pleased to answer any questions you have.

Mr. **Rogers.** Thank you so much. We are grateful to you for being here.

Dr. Carter?

Mr. **Carter.** Thank you, Mr. Chairman.

Doctor, how would a Federal charter affect the day-to-day work of the American Blood Commission?

Mr. **Asfeld.** It would not affect the day-to-day activities of the commission. What it would do is this, the Federal charter would significantly increase the influence of the commission over blood services throughout the Nation. It would show that the purposes of the American Blood Commission, primarily the implementation of the national blood policy, promulgated by the executive branch, would have the endorsement of the Congress, which I think is very important.

Any resulting increased influence would lend weight to the recommendations or the proposals of this particular commission.

[The following information was received for the record:]

American Blood Commission
1901 North Ft. Myer Drive, Suite 300
Arlington, Va. 22209
(703) 522-8414

March 7, 1978

TASK FORCES & COMMITTEES
Donor Recruitment
[illegible]
Regional Association of Blood Service Units
[illegible]
Commonality in Blood Banking Automation
[illegible]
National Blood Data Center
[illegible]
Utilization of Blood and Blood Components
[illegible]

The Honorable Paul G. Rogers
House of Representatives
Washington, D.C. 20515

Dear Congressman Rogers:

During the Hearings before the Subcommittee on Health and the Environment on March 1, 1978, as the witness for the American Blood Commission, I was asked to supplement my presentation in answer to the question, "What advantages would enactment of a bill granting a federal charter to the American Blood Commission provide in terms of the blood processing and supply system of the United States," and to advise as to the status of the legislation.

1. The essential advantage of a federal charter for the American Blood Commission would be the strengthening of the influence of the Commission in accomplishing its mission, which is basically the implementation of the National Blood Policy. That Policy, in turn, is to promote a nationwide system of blood services that will assure an adequate supply of safe blood, from unpaid donors, wherever and whenever it is needed.

2. The reason a federal charter would contribute to that strengthening is that it would indicate Congressional endorsement of the concept that it is appropriate to promote private sector coordination and development of blood resources and services for the Nation. That kind of Congressional encouragement would make the voluntary efforts of the Commission much more effective than the acceptance of the Executive Branch alone.

3. In giving this kind of support for the Commission's aims, Congress would not have to adopt a position on the major issues in which the blood service community are involved. It would be an endorsement of the aims of the National Blood Policy, and a recognition of the American Blood Commission as the catalyst in implementing that policy. It would not indicate sponsorship of any particular method of implementing that policy.

4. A bill to charter the American Blood Commission was introduced in the last Congress and reintroduced on January 11, 1977, in the 95th Congress as H.R. 1687. It was referred to the Committee on the Judiciary and its Subcommittee on Administrative Law and Governmental Relations. That Subcommittee has adopted "Standards for the Granting of Federal Charters," and the American Blood Commission seems to conform to all of those standards. H.R. 1687, along with several other charter bills, is being held in abeyance until the subcommittee receives some explanation, preferably from a Committee of Congress directly involved in the substantive area of the legislation, and from a concerned Executive Department, as to why it should be considered and reported. In January, 1976, the former Secretary of Health, Education and Welfare advised you by letter that his Department "commends the petition to you for favorable action" on the charter bill.

5. The American Blood Commission has carefully considered its activities, since its inception, from the point of view of various National policies and laws.

(a) The Commission and its functions have been determined by the Internal Revenue Service to warrant exemption from income taxation as a scientific and educational organization under Section 501(c)(3) of the International Revenue Code. It has solicitously continued to operate in a manner consistent with that determination.

(b) A federal charter would not add to or detract from the Commission's tax exempt status. The charter is not intended to, nor would it, bring any greater tax exemption, under federal or state law, than it now enjoys as a corporation organized under the local law of the District of Columbia. Similarly, a federal charter would not bring any exemption from any other state or federal law. Its only legal change would be to require annual reports to an appropriate federal government agency instead of to the Register of Deeds of the District of Columbia.

(c) The American Blood Commission is aware that activities of any combination of organizations must conform to the laws applicable to unreasonable restraints of trade. It is conforming to those laws, and it has received advice from the Department of Justice that its purposes, solely as expressed in its articles and bylaws, do not raise questions under the antitrust laws. Since all the activities of the Commission are and have been addressed to the improvement of health care in the nation, by implementing a national, governmental policy, and not to the economic gain of any member organization or individual, there is no reason to expect that there can be any question of infringement of antitrust laws

Sincerely,

L Jadwin Asfeld

L. Jadwin Asfeld
President

LJA:lb

Mr. CARTER. I see. Thank you, Doctor.

Dr. Beck, are our national blood resources adequate to meet the country's needs?

Dr. BECK. I would say that they are not. I think that we need more resources, and I think that we need better resources. This is one of the reasons that we are stressing the importance of research that might turn up with blood substitutes. Also, we are constantly finding new uses for blood, so the needs continue to increase.

Mr. CARTER. You are talking about leukopheresis. How many of these machines do we have in the United States?

Dr. BECK. I don't know. I cannot give you the exact number, but it is small. It is restricted to major centers. It is still very experimental. I know, for example, of only two in Boston. It is still a very small number, and they are not really accessible yet.

Mr. CARTER. It was developed in Houston.

Dr. BECK. That is right.

Mr. CARTER. It takes the different components of the blood and separate them, and allows you to use the components where they are needed.

Dr. BECK. That is right.

Mr. CARTER. Have you considered, Doctor, the institute's efforts to address Cooley's anemia adequate?

Mr. FITZGERALD. We have been very satisfied with the progress that the task force has made. We expect that their report will be finished within the next year.

Mr. CARTER. I would thank you, gentlemen, for your presentations.

Mr. ROGERS. May I ask you, what work do you do in blood in connection with the kidney dialysis program, or is there any connection? Is there a cross?

Dr. BECK. There is. There is, of course, anemia associated with kidney disease, and this is the subject of a great deal of research. Some of it is going on at another institute of the NIH, the Arthritis Institute, where the dialysis program is based. Many scientific problems arise from that complication of kidney failure.

Why is the patient anemic when he has kidney disease? I asked that question in one of my examinations last year. There are, in fact, about a dozen different answers. It is a very complicated story.

This is one of the reasons we are interested in the hormone erythropoietin, which is being studied in the NHLBI. If we can get it purified, maybe we can use it as a treatment for the anemia of kidney disease, the anemia suffered by patients on dialysis.

There are some very important developments along those lines. But we have to get the material, get it cleaned up, and try it out on patients. This is one of the things that is on the docket for future work in this institute. It is a very important development.

Mr. ROGERS. If you could let us have something for the record on that. We will have to check with the institute on that, and see what reaction we are getting. I think that we need to do more research and work on the kidney, particularly where the Government is now paying the majority of the bills, and it will soon be up to $3 billion by 1985. I don't think that we are doing enough in the research arena.

Dr. BECK. May I be clear on what I said? I was speaking of the blood aspect.

Mr. **Rogers.** I think that is a very important part of the overall problem, it would seem to me.

Mr. **Carter.** That is a very important question. We have to know the causes, which really result in crippling conditions of renal performance.

I would like to ask Dr. Beck, or any other member of the panel, what do you think is the most common cause of renal failure, which makes it mandatory for us to do renal dialysis?

Dr. **Beck.** The short answer is that we don't know. I have been interested in this for years. I did my first research back in the late forties with Thomas Addis, who was a great physician and an a renowned expert on nephritis. It is probable that some sort of antibody forms that act against renal tissue. Something similar happens in certain blood diseases, in which antibodies develop against red cells.

There is some evidence that an autoimmune reaction begins to attack parts of the kidney. This is suggested by the fact that nephritis often follows an infection. The evidence on this is still not in, however.

Mr. **Carter.** Streptococcal infection of the throat, I still think that this is one of the major causes.

Dr. **Beck.** I agree with you. Streplococci may elicit antibodies which for some reason also attack the kidney.

Mr. **Rogers.** Here is a question that Mr. Walgren wanted asked, and I think that you might answer that for the record, if you would. We will furnish this question to you, and have it answered for the record, if you don't mind.

Now, let me just ask one final question. Now, has the Federal Trade Commission, or the Antitrust Division of the Justice Department expressed any concern about the American Blood Commission's Federal charter?

Have they expressed any viewpoint on this as to whether there would be any problem or not?

Mr. **Asfeld.** I would like to defer that question to our counsel, Mr. Cardozo.

Mr. **Rogers.** If you could give us a quick answer.

Mr. **Cardozo.** When the Commission was being formed, we asked whether the Department of Justice had any questions on the articles of incorporation; it said that it did not. We have watched this very carefully, and we don't think that there is any antitrust problem.

Mr. **Rogers.** Have they looked at the legislation, Justice or FTC?

Mr. **Cardozo.** We have not consulted them on that, but the Justice Department approved the HEW letter supporting the former bill, and I feel certain that it does not raise any antitrust questions.

Mr. **Rogers.** Thank you so much. We are grateful to you for being here. Thank you so much for your help to the committee.

Now our last witness today is a very patient man, Dr. Benjamin F. Byrd, Jr., past president of the American Cancer Society. I see that he is accompanied by Tanny Polster, who is a friend of the committee.

We welcome you again to the committee. Your complete statement will be made part of the record, and you may proceed as you desire.

STATEMENT OF BENJAMIN F. BYRD, JR., M.D., ON BEHALF OF AMERICAN CANCER SOCIETY

Dr. BYRD. Thank you very much, Mr. Chairman, and Congressman Carter, for allowing me to testify. My curriculum vitae is attached to the statement, for the record. I want to state that I have never been the recipient of any grant or contract from the National Cancer Institute.

First, I would like to talk about the accomplishments of the national cancer program [see p. 253].

First, 29 new anticancer agents have been developed, 6 to 12 of these will eventually prove useful in human cancer. Perhaps three to six will be lifesaving.

The institute got a new director as recently as 1972, and this drug development is an outstanding accomplishment. Any comparable governmental or commercial organization would be proud of that return on investment.

The clinical trials program of the National Cancer Institute has ranged from about $28 million to about $45 million per year since 1971.

By May of last year, Dr. Bernard Fisher was able to report among premenopausal breast cancer patients with one to three nodes positive for cancer, a 26-percentage-point improvement with the drug L-PAM, as compared to controls. Estimated to be disease free after several types of clinical tests were 96.9 percent of the L-PAM patients after 2 years of therapy.

In colon and rectal cancers, surgical removal of the colon and rectal cancers has been the standard treatment. Now we are talking about a combined modality therapy.

In 1977 workers at the University of Indiana used immunotherapy in between courses of chemotherapy on oat cell cancer of the lung. Despite the usual rapid course of this disease, their work produced complete remissions in many cases, absence of tumor, and median survival was almost 1 year, 51 weeks, with 19 patients still alive after being treated for a range of 39 to 113 weeks.

Mr. ROGERS. What page is that on?

Dr. BYRD. It is around page 5 or 6.

Mr. ROGERS. These are the kinds of statistics that ought to be made clear to the Congress. I might suggest that you might want to get those statistics, and send them to Members of the Congress, so they would know what is happening in this field.

Dr. BYRD. We would be delighted.

In bladder cancer, a Queens University group in Ontario found 35 lesions of a recurrent nature after initial treatment in a study of 67-patient-months' experience, but when direct inoculation of the tumor with immunotherapeutic agents there were no recurrences at all in 47-patient months of followup.

At Northwestern University 17 stage III and stage IV patients were given a 2-week course of drugs before surgery and radiotherapy. Ten patients with stage IV, and 7 patients with stage II, were treated for 2 years, after which 4 patients had died, 1 was alive with a tumor, and 12 were disease free. A remarkable record for patients of that staging.

Since this was reported last year, another 40 patients' experience has been entered into the study and the preliminary results are being duplicated in the larger group, which now has a median patient term in the study of 12 months.

The fact is, Mr. Chairman, that the national statistics are quite a bit behind the facts of our best clinical experience, because data collecting on a national basis is difficult and time consuming, if it is to be accurate.

I give other examples in my written statement about outstanding results of clinics. The longer statement addresses these areas, with the expected new cases in 1978: Breast cancer, 90,700; colon-retal, 102,000; lung, 102,000; bladder, 30,000; Hodgkin's disease, 7,400; and kidney and other urinary, 15,000.

Last year, the Metropolitan Life Insurance Co. statisticians published in a very clear way, using government data, the survival rates for 15 years of various cancers in women in all age groups, starting with 45 years old. Unfortunately, this covers only white women, and we know that the rates are not so good for others.

The figures are impressive for the 15-year level of management for localized cancers:

Cancer of the breast, 69 percent; stomach, 37 percent in 10 years, the 15 years not being available; colon, 67 percent; rectum, 59 percent; lung and bronchus, 38-percent survival at 10 years, the 15 years not being available; ovarian cancer, 65 percent; bladder cancer, 66 percent; uterus: cervix, 70 percent; and corpus, 80 percent.

Metropolitan Life also measured the death rate for all types of cancer among its policyholders in 1976, and found that the rate had fallen 3 percentage points below the 1971–75 level.

It is clear that a reversal may be underway, despite the huge increase in deaths from cancer related to cigarette smoking.

Mr. Chairman, we need a Presidentially appointed director for the National Cancer Institute and Presidentially appointed members of the National Cancer Advisory Board.

If delay is the reason for bringing the appointments down to the secretarial level it is clear from recent experience that such delays will continue in any case. The council meetings at NIH were plagued with this problem this January, despite secretarial level appointments. The National Eye Institute called back three members whose terms on their council had expired so that they could hold a full council meeting.

If the reason is that the same caliber of persons will be selected, I have my doubts. We found the intercession of the men on the President's Cancer Panel and on the Board extremely helpful in the White House when training was the issue. Secretary Weinberger was adamant in cutting back research training. But NCI had been expanded sharply and simply could not do what it was charged to do without an adequate training program.

We have a difficult time finding directors as it is now. We need directors and board members with the public affairs and administrative background necessary for success in the kind of communicating and negotiating that goes on at the OMB and White House level.

After a tremendous amount of conferring, planning, and other assignments, resource data from community hospitals and medical schools, volunteers and public health associations have put their reputation on the line, they have sought and won commitments for programs and resources, and they have created pipelines.

The 30-member Public Issues Committee of the American Cancer Society met on February 2, 1978, and among other work, heard a report on the National Cancer Institute's budget. Our committee, on which I serve as cochairman, includes scientists, physicians, laymen, women devoting their time primarily to raising a family, faculty members from Howard University and the Institute for Advanced Studies at Princeton, among others.

After discussion, the group recommended, and the society's board later supported, a fiscal 1979 budget for the National Cancer Institute above the authorization level allowed by H.R. 10908.

We are deeply concerned about the waste of past investment which will take place if activities already in motion are brought to a premature halt. This happens with disturbing frequency in the Federal picture, and as you know, fortunately not as often in the jurisdiction of this subcommittee as in the jurisdiction of other subcommittees of the Congress.

We are dealing with the careers of young researchers, young physicians, and with men who have spent decades shaping and pruning their programs in research, education, and treatment. To turn off the tap, to leave those pipelines dribbling, instead of carrying a good fiscal flow, would be one more action, after too many such actions, highly discouraging to everyone involved.

My main concern is with the response to this important piece of Federal health leadership. I know that this subcommittee has struggled manfully with the problems of change and lack of change in the health care world. I am heartened by your many successes but also feel that the response to your leadership would be clearer, quicker, more definite if those in the ranks were convinced that the leadership is firm, unshakable, consistent. I do not think that the cancer community across the country will receive that impression if the authorization limits in H.R. 10908 are enacted.

The National Cancer Advisory Board has probably been closer to this question than any other group anywhere. They have approved $1.2 billion in authority for fiscal 1979, support more than $1.3 billion for fiscal 1980, and nearly $1.4 billion for fiscal 1981.

The Board, moreover, is reconsidering the latter 2 years' figures and could come up with higher authorization requests within the wisdom provided by continuing and intimate contact with the conquest of cancer program and all of its component parts.

If we trace the appropriations back to the middle of the decade before the National Cancer Act first passed, back to 1965, then we see the total of all NIH institutes, other than cancer and mental health, was $563 million.

In the 6 years between then and the passage of the National Cancer Act in 1971, the total, minus NCI and NIMH, went to $879 million in appropriations, a 56 percent increase. In the 6 years following the passage of the act, the same Institutes' appropriations reached $1,453 million, or a 65 percent increase in the 6 years following the act compared to 56 percent before the act. They did better after than before.

Cancer is the second biggest killer, as we all know, but probably the biggest drain on the health care budget. A patient with cancer, on the average, costs over $20,000 according to gross estimates.

It is clear that, conservatively, the cost of cancer in this country is ranging from $25 billion to $35 billion. This is coming out of our pockets. It is not imaginary.

Measured against the disease problem, against what other NIH institutes have experienced in recent years, against original plans of the National Cancer program set in motion by the Congress, an authorization figure of $1.2 billion is certainly not too much for NCI in fiscal year 1969, going to $1.4 billion in fiscal 1981.

Following a national chemical carcinogenesis testing program that has received a great deal of exposure, there has been slow progress in reaching conclusions on the dangers of various carcinogens found in the atmosphere of cities, factories, and workplaces, products for use by the consumer, or industrial use, or pesticides.

It is my belief that when today's hue and cry dies down, we will still face many scientific questions for applied research on product safety from carcinogens. We know too little today. We are faced with highly conjectural situations on the basis of animal data. We need better data in the human situation.

There is the often quoted cliche, The National Cancer Institute, and the American Cancer Society, far underrate the problems inherent in the flow of chemicals. Attached to this testimony is proof positive that both organizations have alerted the Nation to the very dangers that some journalists say NCI and ACS are collaborating to conceal.

The scientific difficulty in approaching these environmental problems is enormous. The Cancer Institute found this out when it began on a project to define and commence study of the flow of chemicals into the environment. The entire program cannot be judged on the basis of the lack of conclusive achievements in this area.

Supervision of contract work has been difficult with the workload which went up 359 percent, and the work staff went up 57 precent.

Mr. Chairman, the Institute has not been idle. It has produced scientific reports in four volumes in recent years. The title of the volumes is: "Survey of Compounds Which Have Been Tested for Carcinogenic Activity." Study after study, thousands of them, are there.

The problem is really one of interpretation, translation of animal data to man, interpretation of the danger to man even when we know the facts of animal experimentation. The process of carcinogensis seems to take 20 years or more, in some cases. We don't know. The best scientists will withhold judgment for many years under these circumstances.

For the public to demand more, that is worse science, means that decisions, regulations, even construction and preventive measures of many sorts will be a drain on precious resources for dubious purposes, an invasion of other important program budgets where demonstrable benefits might issue.

Mr. Chairman, Dr. Jonathan Rhoads is an outstanding physician, administrator, educator, and has been named Man of the Year in

Philadelphia for his civic work apart from all his other duties. He needs to bow to no one for his rewards. They are based on his service —this achievements.

He has been Chairman of the National Cancer Advisory Board since the conquest of cancer program began. He ends that service now. In a statement to the Public Issues Committee of the American Cancer Society 2 weeks ago he said what I think is the best wisdom we can adopt at this point in medical history:

> I must leave it to you to judge whether the program in cancer which the American Cancer Society did so much to accelerate 6 years ago has been worthwhile. I think that if we had not started it then, we would certainly be doing so now.

We do not need to start now for we are well along on our journey to the control of cancer in our country. This program needs the opportunity to continue with adequate support and without a tearing distortion of its basic structure toward the goal for which we all hope and search.

[Testimony resumes on p. 289.]

[Dr. Byrd's prepared statement and attachments follow:]

Statement

of

BENJAMIN F. BYRD, JR.

Past President

AMERICAN CANCER SOCIETY

Before the

95th Congress
United States House of Representatives
Committee on Interstate and Foreign Commerce

Subcommittee on Health and the Environment

1 March 1978

Mr. Chairman and Members of this Subcommittee I want to thank you for the special scheduling of my testimony that you have arranged and, in fact, for the opportunity to give you my own personal comments about the National Cancer Act and to present the Americn Cancer Society's position on the extension of the Act.

For the record, my personal views stem from my private practice of surgery, from my teaching at Vanderbilt University and also at Meharry Medical College. My view of the cancer control program is shaped partly by my work as Director of the Extramural Program of the Vanderbilt University Hospital Cancer Center. My view of community hospital cancer activities comes from St. Thomas Hospital in Nashville where I am President of the Medical Staff, from Nashville's Baptist Hospital where I am an attending surgeon, from my experience as regional consultant to the Veterans Administration and from Metropolitan Hospital in Nashville.

Beyond these individual appointments and experiences I have served as Chairman of the Commission on Cancer of the American College of Surgeons. This commission has maintained what some people would term a technology transfer activity for many years. This commission's work started before the current National Cancer Act was passed and has expanded and changed as the entire world of cancer therapy has responded to new ideas and new technologies, particularly since the passage of the new Act in 1971.

I should be happy to accept questions concerning the American Cancer Society since I am a Past President, which means as you know that I served in many different roles before being elected to that post. I am currently Co-Chairman of the Society's Public Issues Committee which was created just this year as an instrument to formulate and present the position of the American Cancer Society in matters of importance to the public generally.

I want to make sure that this record contains the fact that I have never been a principal investigator on a National Cancer Institute grant; have never been an NCI contractor; and have not served on any program where a major portion of the funds come from NCI. All of my work is in the private sector. We have received on occasion minor support and have cooperated with NCI.

While Vanderbilt, Meherry, and other institutions in which I serve may discharge their responsibilities without NCI it is my personal view and the American Cancer Society's position that the Conquest of Cancer program is good for our country. Like other NIH research NCI's benefits all of society, but of this research practically none is commercially profitable and would not be done if society as a whole, the government that is, did not support it.

Along with a multitude of educational, service, community organizing and other activities the American Cancer Society supports some $36½ million in research. NCI's budget is running about $872 million.

Attached to this statement is the January 15, 1978, issue of NCI's Division of Cancer Treatment Newsletter. For physicians working at the research/treatment interface it sums up the current drug situation, which is in need of explanation to them because of ongoing negotiations between NCI and the Food & Drug Administration to speed drugs to test and to patients faster.

Not counting new formulations of old drugs, 29 new agents have passed all the animal tests and have been approved by FDA for preliminary human trials. It is estimated that only 6 to 12 will eventually prove useful in human cancer. Perhaps 3 to 6 will be lifesaving. Considering the fact that a director of the National Cancer Program was appointed only in 1972 this is an outstanding accomplishment.

It could take another 5 or 10 years for these drugs to reach patients generally, but that is not the fault of the cancer program. It is a manifestation of the caution which, currently exists under our food and drug laws.

The clinical trials program of the National Cancer Institute has ranged from about $28 million to about $45 million since 1971. So the modest funding, cast against the background of an enormously complicated medical enigma, has resulted in useful knowledge and therapy that any comparable organization, commercial or governmental, anywhere, would consider outstanding.

Mr. Chairman, I would like to call this committee's Attention to some truly meaningful advances in chemotherapy.

In 1971 the median survival for patients with disseminated breast cancer was 8 - 10 months. When Adriamycin came in the median survival for this advanced form of cancer became 14-15 months. With combination chemotherapy plus BCG immunotherapy the median survival is in excess of 22 months.

The few months' increase becomes very important in the overall perspective as I will show shortly.

In stage III (locally advanced) breast cancer with positive lymph nodes data as of 10 months ago showed that combination chemotherapy (cytoxan, methotrexate, 5-FU) patients three years after treatment began 89.6% of the patients were alive after three years while 78.6% of the control patients survived that long, an improvement of 11 percentage points.

By May of last year Dr. Bernard Fisher was able to report among premenopausal breast cancer patients with one to three nodes positive for cancer a 26 percentage point improvement with the drug, L-PAM,as compared to controls. Estimated to be disease free after several types of clinical tests were 96.9% of the L-PAM patients after two years of therapy. In postmenopausal patients with one to three nodes positive for cancer the improvement was smaller, 2.2 percentage points, but still there was 88.2% survival after two years. Not only was that improvement small, but L-PAM for postmenopausal patients might not be the drug of choice since those patients with involvement of four or more nodes survived for two years at a few percentage points -- 61.5% compared to 59.7% -- if they were in the control group better than if they were in the L-PAM group.

There's been comment in the press repeatedly about the absence of real progress in cancer therapy. Yet in colon and rectal cancer, solid tumors which casual observors . tell us is an area of no progress, have shown significant response to treatment. Surgical removal of the colon and rectal cancers has been the standard treatment for decades. It is essential now. Adding to it chemotherapy and immunochemotherapy has doubled the survival time in one study as compared to surgery alone. In another study the effectiveness of short term fluorouracil chemophrophylaxis, preventive medicine after surgery, was evaluated and it was found that Stage III (Duke's class C) patients, 213 of them, five-year survival moved from 24.3% under surgery, alone, to 57.5% with flurouracil. Even better results were achieved with patients whose cancers were not so far advanced. I emphasize, the data refer to five-year survivals.

These are not peripheral cases. In 1978 there will be an estimated 102,000 new cases of colon-rectal cancer. But these cases will fare better than cancer patients have ever fared before. An estimated 51,900 will die of colon-rectal cancer in 1978 whose treatment began when research results were not as far along as they are now.

In 1977 workers at the University of Indiana used immunotherapy in between courses of chemotherapy on oat cell cancer of the lung. Despite the usual, rapid course of this disease, their work produced complete remissions in many cases, absence of tumor, and median survival was almost one year, 51 weeks, with 19 patients still alive after being treated for a range of 39 to 113 weeks.

In a study published two years ago Stage I squamous cell cancer and adenocarcinoma showed the advances made in early diagnosis so that surgery alone resulted in 77% survival after one year and surgery plus BCG administered intrapleurally, or directy into the lung cavity, produced 100% survival after one year.

Mr. Chairman, these kinds of results -- in a disease, lung cancer, which still kills 92,400 persons per year -- could not be reported when the National Cancer Program began.

In bladder cancer, a Queens University group in Ontario found 35 lesions of a recurrent nature after initial treatment in a study of 67 patient-months' experience, but when direct inoculation of the tumor with immunotherapeutic agents there were no recurrences at all in 47 patient-months of follow-up.

Surgery, again, is the essential treatment in most head and neck cancer, but new methods are showing true improvements. At Northwestern University 17 Stage III and Stage IV patients were given a two-week course of drugs before surgery and radiotherapy. After being in the study a minimum of two years, 4 patients had died, one was alive with a tumor, and 12 were disease free, a remarkable record for this group of patients, 10 of whom were Stage IV and 7 were Stage III. Since this was reported last year another 40 patients' experience has been entered into the study and the preliminary results are being duplicated in the larger group, which now has a median patient term in the study of 12 months. Mr. Chairman, we are talking about over 70% disease free after two years in the preliminary group. These are not the kind of percentages one would gather are being experienced if one were to go by newspaper articles.

Much of this information comes from a 105-page compilation by a researcher at M.D. Anderson Hospital of Houston, and was supplied to your committee staff when it was produced in late 1976. It was updated in May of last year. We shall be happy to supply the book to any Member of the Committee who wishes one.

Of course the premise of the Conquest of Cancer program in 1971, as recalled recently by Dr. Jonathan Rhoads, "Was that knowledge had advanced to the point at which a large stepup in support could be expected to augment the benefits derived from the (existing NCI) program." He pointed out that important results from the Conquest program stemmed from work done earlier. He concluded that The change in prognosis for Hodgkin's disease has been almost as great as the change in prognosis from subacute bacterial endocarditis was with the introduction of intensive penicillin therapy. From a prognosis of virtually zero recovery,"he said, "we have a majority of the patients surviving five, ten and more year."

He called Wilm's tumor of the kidneys in children "a classic example of the usefulness of therapy involving different modalities of treatment. Originally the disease was treated by surgical excision of the diseased kidney with a 30-40% five-year survival rate." Dr. Rhoads is a surgeon. "To this was added radiation," he said, "which put the survival rate in the 60% range. And now, with the addition of chemotherapy, survival rates gave gone to 75% approximately," he concluded.

This Committee has heard before the story of how lethal doses of methotrexate are administered to bone cancer patients along with citrovorum, a rescue factor, antibiotics, platelet transfusions and leucocyte transfusions as necessary. The historical rate of two-year survival for osteogenic sarcoma was about 20-25%. It is now above 95% and, when more time has passed, the much longer term survival can be documented, the scientists are convinced.

Mr. Chairman, obviously I have not mentioned all of our successes. But the ones I have mentioned are not confined to minor cancers, as so often is reported.

Here are the cancers I have mentioned and the new cases estimated to arise this year:

Breast cancer -- 90,700
Colon-rectal -- 102,000
Lung -- 102,000
Bladder -- 30,000
Hodgkin's disease -- 7,400
Kidney & other urinary -- 15,100 (includes Wilm's tumor of children)

I do not tell this Committee that we are now curing all of these patients. I say that tens of thousands are experiencing useful years of life extension. We have, in fact, brought to this Committee's attention the need for new legislation to provide accommodation with Medicare or Medicaid for the growing number of patients on continuing chemotherapy who want to continue working, living with their families, going to college, or otherwise pursuing the business of living. What they provide society makes their medical care very worthwhile in numerous cases.

More and more, many of us are finding among our friends recovered cancer patients. I predict that, in coming years, this Committee will spend important hearing days and bill writing days on the subject of the ex-cancer patient's position vis à vis employment, insurability, and educational opportunity.

While the movement of government statistical reports is more ponderous, the Metropolitan Life Insurance Company's reporting comes up to very recent years. The first half of 1976, as compared to the first half of 1975, showed that death from cancer among the company's policy holders fell by 5%. When the entire year, 1976, was finished, there was still a decline, 3%, in deaths from cancer as compared to the 1971-1975 experience.

Last October the Metropolitan Life statisticians put National Cancer Institute data into a new array and showed the following 15-year survival rates for various cancers in women of all age groups starting with 45 years old:

Breast	69%	
Stomach	37%	(10 years; 15 not available)
Colon	67%	
Rectum	59%	
Lung & Bronchus	38%	(10 years; 15 not available)
Ovary	65%	
Bladder	66%	
Uterus		
Cervix	70%	
Corpus	80%	

Unfortunately, these data refer only to white women. We know that the survival rates among blacks is lower. Also, the above figures tell the story only where prompt detection found a localized cancer. Where all stages of the disease were rated, the survival rates fall, of course. Even so, the 15-year survival rate for white women with breast cancer, all stages, was 44%, with similarly hopeful data for the other organ sites. All of these data describe relative survival, that is, adjusted for deaths from other causes so that the impact of cancer, alone, can be estimated.

The excellent results which have been reported to you could not have been achieved if, time and again, this program weren't aided by the President's Cancer Panel. Particularly in the earlier stages of the Conquest of Cancer effort there were frequent needs to move with vigor at the departmental and White House levels.

For instance, the Congress through the National Cancer Institute put in motion a quantum expansion in the program at a time when the Office of Management was phasing out the training of biomedical researchers. Secretary Weinberger was particularly insistent on this phaseout. Only a full presentation of the situation by the President's Cancer Panel at the White House worked out the total contradiction between the expansion and contraction policies. There were other occasions where, I am sure, members of the Panel could tell you that they were instrumental in redirecting the Conquest of Cancer program to fit policy developed above the NIH level or vice versa.

Mr. Chairman I am not at all sure that appointment by the HEW department of the National Cancer Institute director and board members would attract the men and women with the public affairs and administrative background necessary for success in this kind of communicating and negotiating.

It is my belief that the government can certainly get someone to work in these unpaid jobs a whole lot easier and more effectively through Presidential than through Secretarial appointments.

In terms of the discretionary money involved, the National Cancer Program is one of the largest in the federal government. We need the very best leadership we can attract.

It is true that there have been delays in appointments.

But the National Institutes of Health has had to scramble in recent months because appointments by the secretary were tardy. For instance, in the National Eye Institute the January meeting of the National Eye Advisory Council was convened with three former members of the council because the secretary had not promptly appointed their successors. They were supposed to be appointed in November and no one has yet been announced for these positions though I am told the Secretary has signed off on one of the three. The same is true in some other institutes.

The Congress in its wisdom determined to try a new type of biomedical research and disease prevention administration when it adopted the Conquest of Cancer program. The six years since the program began is a very, very short time, indeed, as biomedical programs go. Certainly at least three more years under the original concept are needed to see if this new type of administration is what you in the Congress perceive as most productive. It is clear that the old system begs many a question.

Downgrading the cancer program leadership by taking the director's and member's of the board appointments from the Presidential level and putting them at the secretarial level, in our opinion, might damage the program and we see no need to take that risk at this time.

The 30-member Public Issues Committee of the American Cancer Society met on February 2nd, 1978 and, among other work, heard a report on the National Cancer Institute budget. Our committee includes scientists, physicians, laymen, women devoting their time primarily to raising a family, faculty members from Howard University and the Institute for Advanced Studies at Princeton, among others.

After discussion the group recommended and the Society's board later supported a fiscal 1979 budget for the National Cancer Institute above the authorization level allowed by H.R. 10908.

We are deeply concerned about the waste of past investment which will take place if activities already in motion are brought to a premature halt.

This happens with disturbing frequency in the federal picture, as you know, fortunately not as often in the jurisdiction of this subcommittee as in the jurisdiction of other subcommittees of the Congress.

We are dealing with the careers of young researchers, young physicians, and with men who have spent decades shaping and pruning their programs in research, education and treatment.

It took two or three years for many in the biomedical community to become convinced that the Congress meant it when it enacted the National Cancer Act of 1971. It then took some participants years to explore their own work to see how it could legitimately apply to the cancer questions. Careers have been adjusted. Some construction has taken place. Departments have been reorganized. Entirely new vistas have come into view through outreach, technology transfer, continuing education, critical self-examination of procedures considered routine for years -- X-ray diagnosis for example -- and centers in many areas have developed after dozens of conferences, seminars, planning sessions, and false starts, working relationships with community hospitals, medical schools, voluntary health organizations including the American Cancer Society. The leaders in this always difficult work have put their reputations on the line. They have sought and won commitments of program and resources. They have created pipelines.

To turn off the tap, to leave those pipelines dribbling, instead of carrying a good fiscal flow, would be one more action, after too many such actions, highly discouraging to everyone involved.

My main concern is with the response to this important piece of federal health leadership. I know that this Subcommittee has struggled manfully with the problems of change and lack of change in the health care world. I am heartened by your many successes but also feel that the response to your leadership would be clearer, quicker, more definite if those in the ranks were convinced that the leadership is firm, unshakable, consistent. I do not think that the cancer community across the country will receive that impression if the authorization limits in H.R. 10908 are enacted.

The National Cancer Advisory Board has probably been closer to this question than any other group anywhere. They've approved $1.2 billion in authority for fiscal 1979, support more than $1.3 billion for fiscal 1980, and nearly $1.4 billion ($1.380 bil.) for fiscal 1981. The Board, moreover, is reconsidering the latter two years' figures and could come up with higher authorization requests within the wisdom provided by continuing and intimate contact with the Conquest of Cancer program and all of its component parts.

If this sounds like a lot of money, look at it in the traditional way that the Congress regards NIH spending.

If in fiscal 1979 the Congress were to appropriate $900 million for the National Cancer Institute the administrators at the institute tell us that there would likely be attracted about 1,900 regular program research projects which would be approved by the peer system. But the $900 million would only fund a bit more than a third of them, about 647 grants worth $54,929 million. That would be 34.5% funded of all approved.

Even at a $1,036 million level, a total the institute favored in its negotiations with OMB and which the American Cancer Society supports, only 925 grants would be funded and the percentage would still only be 49.3% of those apppoved, not at all out of line with the levels at other NIH institutes.

H.R. 10908 would not allow that level of funding.

The Conquest of Cancer program has been under attack from some quarters ever since the concept was presented to the Congress, and almost always by the same people. The basic charge has been that the cancer program has drained money from others in NIH.

The facts are otherwise.

If we trace the appropriations back to the middle of the decade before the National Cancer Act first passed, back to 1965, then we see the total of all NIH institutes (other than cancer and mental health) was $563 million. In the six years between then and the passage of the National Cancer Act in 1971 the total (sans NCI and NIMH) went to $879 million in appropriations, a 56% increase. In the six years following the passage of the act, the same institutes' appropriations reached $1,453 million, or a 65% increase in the six years following the Act compared to 56% before the Act. They did better after than before.

Incidentally, if we bring that table up to date, fiscal 1978, the increase for those institutes since the passage of the Act becomes 91½%.

In terms of shares, the National Cancer Institute accounted for 86% of NIH's budget in 1938 and the total ranged as low as 16% in the next 20 years as new institutes were created. It stood at 23% in 1958 and went down to 12% in 1967. So the share has vibrated quite a bit over the years. The present 34% is not at all unusual. When we had practically the NIH we have today, during the 1948 to 1953 years, the range went all the way from 30% to 50%.

Cancer is the second biggest killer, as we all know, but probably the biggest drain on the health care budget. A case of cancer, on the average, costs over $20,000 according to gross estimates and according to a detailed study by Dr. John Spratt in the cancer center at Columbia, Mo.

With an estimated 700,000 new cases of cancer in 1978, the case cost would total $14 billion.

It would appear that the work-time lost, and earnings lost through premature deaths would total another $10 billion to $20 billion, though the statistical methodology for this calculation is under question. A crude factoring of the average wage, plus an imputed wage for the housewives and househusbands, coupled with premature death figures gave a $17 billion earnings lost in one calculation made three years ago.

It is clear that, conservatively, the cost of cancer in this country is ranging $25 billion to $35 billion. This is coming out of our pockets. It is not imaginary. Anyone with a death of a wage earner in his family sees this loss tangibly. We talk about balancing the budget, meaning the federal budget. That can be dangerously narrow thinking if we simply unload public and private sector responsibilities one way or the other. The sophisticated calculation is to look at the overall costs and see what we can save the nation. One or two billion dollars per year against a $30 billion problem doesn't seem like overspending. The cost of care of 50,000 cases of cancer -- and we expect 700,000 this year -- is $1 billion. It is quite likely that our patient salvage rate is, in fact, paying for all of NCI's research through avoidance of worktime lost and premature deaths.

Measured against the disease problem, against what other NIH institutes have experienced in recent years, against .original plans of the National Cancer Program set in motion by the Congress, an authorization figure of $1.2 billion is certainly not too much for NCI in fiscal 1969, going to $1.4 billion in fiscal 1981.

It would, of course, be less than candid of me to tell this Committee that the National Cancer Program has been faultless. No program this size is. My own feeling is that it suffers many of the common ailments of large government programs.

On the other hand criticism of the Conquest of Cancer program has been sensational and damaging. It is conceivable that some of this criticism where poorly based has increased morbidity and mortality.

The most obvious case is the breast cancer mammography. The first scarehead notice in the paper,"Panel Told of Needless Breast Removals," said flatly, "Fifty-three women in a federal cancer detection program had breasts removed needlessly for what turned out to be noncancerous conditions, a panel of scientists told the National Cancer Institute yesterday."

The failure to qualify that statement in the press the way it was qualified upon delivery was part of a chain of events which discouraged thousands of women from getting their scheduled checkups.

The truth of the matter, after very detailed investigation, which was indicated as forthcoming at the time of the original announcement, is that any concern relates to no more than 3 of the 2,487 breast tumors detected by mammography. Considering the hazards of reading pathological slides, the difficulties of coming to undisputed conclusions on the basis of a continuing program, 3 out of 2,487 is a record of commendable responsibility, a real team interest in arriving at a judgment most meaningful to the patient. The full and reliable news report on the outcome of this controversy is attached to this testimony.

It is interesting to note that the very existence of the Conquest of Cancer program made it possible rapidly to revise the situation once it was identified. Radiation dosage was not in the most extreme view a manifestation of fault introduced by the cancer program. Rather it was endemic in the medical care delivery system. Some mammography units in the screening demonstration were operating at optimum levels. When criticism came the quick response went immediately to the screening units, but also the Bureau of Radiological Health of the Food & Drug Administration, which always had jurisdiction, became more active. After viewing the radiation controls in the Demonstration Projects, several states invoked within their borders universal checking of X-ray equipment.

This justified criticism was quickly met with remedial action and the entire medical care system is more sensitive to the danger and the patients are better off. I do not think that, without the Conquest of Cancer program, the responsibility would have been so apparent and action so rapid. It is when we are all trying to do something vigorous, progressive, helpful, that we learn and improve.

As usual, the more extreme views of the systen were forthcoming from extremists. Maybe it would be useful for this Subcommittee to note that the average mammography exposure is down to 0.5 rads, and that to a circumscribed portion of the whole body. In Denver, Colorado,it is estimated that residents get some 70 rads of extra radiation to the whole body in a lifetime just from cosmic rays. This works out mathematically to a greater risk from merely residing in the mountain area of highly actinic light than from mammography for a woman who undergoes the procedure every three months between the ages of 30 and 70 and no demonstration project anywhere asks that of a woman.

Another fault of the National Cancer Program which has received a great deal of criticism has been the slow progress in reaching firm conclusions on the dangers of various carcinogens found in the atmosphere of cities, near factories, in work places, and in products in wide consumer or intermediate industrial use, such as pesticides.

It is my belief that in spite of much of today's hue and cry we will still face many years of applied research before product safety from carcinogens can be designed.

We know too little today.

We are faced with highly conjectural situations in the translation of animal data to the human situation.

Regulatory processes can be highly expensive and raise the cost of living in a country with a serious and chronic problem of poverty.

It is not just a matter of balancing risks and benefits. Even assuming the worst risks and the least benefits from some of the questionable products today, the problem of what to do in given situations is probably frequently more demanding of science than science can respond to. The regulation writing procedures under way today point this up.

While consumers, government administrators, scientists, and statisticians struggle with the real problems, the journalists have often conjured specious ones.

There is an oft expressed cliche that the National Cancer Institute and the American Cancer Society far underrate the problems inherent in the flow of chemicals into our environment.

Attached to this testimony is proof positive that both institutions can take great credit for alerting the nation to the very dangers that some journalists say NCI and ACS are collaborating to conceal.

As for NCI, in 1970 in a widely circulated report entitled "Progress Against Cancer" half of the material was on chemical carcinogenesis. Said the report, "Ecologists... have warned that man is jeopardizing his very survival by continuing to pollute his environment..." And later, on page 17, "Only a very small fraction of the hundreds of thousands of man-made substances, biological wastes and other pollutants, that have been added to the environment has been tested for toxicity to these marine diatoms (which are a part of the earth's source of oxygen)"...And on page 18, "Experts suspect that the increase in cancer is related in large measure to an increase in exposure of the population to cancer-causing agents in the environment."

This report was a prestige display piece of the National Cancer Institute and was probably its most widely distributed publication when it came out eight years ago.

While the American Cancer Society is not here asking for anything the same journalistic charges have been entered against the society. As a matter of fact, under the law, the National Cancer Institute is charged with the responsibility of bringing into the National Cancer Plan the fullest possible participation of voluntary health associations and we have been proud to put some of our donations into joint ACS-NCI projects. The Society, too, has been indicted by journalists for insensitivity, even opposition to the idea that man is creating his own death dealing substances and selling them to his fellow man.

The truth is completely the opposite. A search and respect for the facts by any fair minded person will show that the hue and cry over carcinogens today is attributable very importantly to scientific work and announcements by the American Cancer Society years before the faddist came to the fore. With the late Rachel Carson and the National Cancer Institute, the American Cancer Society has probably produced the most telling research that has brought this country to realize carcinogenic dangers. I cite the 1972 Archives of Environmental Health article by Irving Selikoff, who got support from the American Cancer Society, and E. Cuyler Hammond, ScD, who was on the Society's payroll, and Jacob Churg, MD, entitled "Carcinogenicity of Amosite Asbestos."

I cite by the same authors "Asbestos Exposure and Neoplasia" in JAMA of April 6, 1964, hardly a Johnny-come-lately article.

I cite a Selikoff and Hammond article in the American Journal of Public Health of September 1968 titled, "Community Effects of Nonoccupational Environmental Asbestos Exposure." There were other articles and the study of this clear and present danger continues, and continues to receive Society sponsorhsip.

The Society's Hammond in fact testified on July 30, 1968, before the Subcommittee on Air and Water Pollution of the Senate Committee on Public Works and said, "There is reason to suspect that air contaminants of almost all types can, in high amounts, be injurious to health." He said, "It is now urgent that pertinent environmental data on air pollution (both general and neighborhood) be collected and correlated with data on the health of individuals."

I could cite other articles and testimony regarding vinyl chloride and benzpyrene. The record is one totally of trying, and it is clear, succeeding in alerting the people of this country to extremely dire health dangers.

What is to be done about those dangers is another matter. Hammond has intensively studied the epidemiological evidence that automobile fumes in high concentrations cause the incidence of cancer to be inflated. So far the evidence is negative, no matter how much we all might agree on other grounds for reducing fumes. In the absence of a reliable science base regulatory action is certainly fraught with delay, difficulty, conflict and irresolution.

Other cancer society-supported research casts doubt on the carcinogenic effect of sidestream cigarette smoke. Therefore the Society is very circumspect in its statements about danger from the other person's smoking. We stick with the scientific evidence and leave the decision to smoke or not to smoke to individuals. We do not call for prohibition.

The scientific diffiulties in approaching these environmental problems are enormous. The cancer institute found this out when it began on the project it defined, itself, of commencing testing the flow of chemicals into the environment.

The entire program cannot be judged on the basis of the lack of conclusive achievements in this area. Supervision of contract work has been difficult where the workload went up 47% to 359% while the work staff went up 57%.

OMB has worked hard to keep down federal employment and I am sure that most taxpayers applaud their efforts. In this case the overworked staff has had a very difficult time supervising the work of grantees and contractors. Site visits, report analysis, evaluation, checking on schedules, challenging delays, these are things that need to be done and should be done and, as we have learned, in some cases weren't done effectively.

It is interesting to note that at the last National Cancer Advisory Board meeting the limits of scientific penetration of the problem were perceived and the unanswered questions for regulation, for advice, were faced, but progress was admitted to be slow and unpredictable.

Mr. Chairman, the Institute has not been idle. Earlier today I hefted 19 pounds of scientific reports from NCI, four volumes, I show you one, here, produced in recent years. The title of the volumes is "Survey of Compounds Which Have Been Tested for Carcinogenic Activity." Study after study, thousands of them, are in here.

The problem is really one of interpretation, translation of animal data to man, interpretation of the danger to man even when we know the facts of animal experimentation.

Cancer generation seems to take 20 years or more in most cases. We don't know. In the best spirit of science, all scientists will withhold judgment for many years under these circumstances. For the public to demand more, that is worse science, means that decisions, regulations, even construction and preventive measures of many sorts will be a drain on precious resources for dubious purposes, an invasion of other important program budgets where demonstrable benefits might issue.

Where the signals are clear, of course we must proceed with despatch. I don't think there is any record of reluctance in this sense on the part of the National Cancer Institute. That is why we support the continued healthy funding of the National Cancer Program.

Mr. Chairman, Jonathon Rhoads is an outstanding physician, administrator, educator, and has been named the Man of the Year in Philadelphia for his civic work apart from all his other duties. He needs to bow to no man for his rewards. They are based on his service; his achievements.

He has been Chairman of the National Cancer Advisory Board since the Conquest of Cancer program began. He ends that service now and in a statement to the Public Issues Committee of the American Cancer Society two weeks ago said what I think is the best wisdom we can adopt at this point in medical history. He said, "With this brief review," he summed up a half-hour speech, "I must leave it to you to judge whether the program in cancer which the American Cancer Society did so much to accelerate six years ago has been worthwhile. I think that if we had not started it then we would certainly be doing so now."

We do not need to start now for we are well along on our journey to the control of cancer in our country. This program needs the opportunity to continue with adequate support and without a tearing distortion of its basic structure toward the goal for which we all hope and search.

DCT NEWSLETTER

NUMBER 4, JANUARY 15, 1978

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DCT ANNOUNCEMENTS

Investigational Drug Distribution

The Division of Cancer Treatment (DCT) has redesigned its protocol acceptance/drug distribution policies during the past year to comply with FDA regulations and to maximize the amount of information obtained from studies with drugs under IND sponsorship by DCT (originally reported in *DCT Newsletter Number 2*).

The new system, while directed toward research, is also responsive to the needs of practicing oncologists in situations where certain investigational new drugs may be needed for therapy. In addition, it will facilitate implementation of investigational drug research programs at comprehensive and clinical cancer centers.

Basically, these changes have been produced by classifying drugs into three categories which correlate with protocol acceptance/drug distribution policies.

1. **Group A** includes drugs in their initial phases of clinical evaluation. Their distribution is limited to studies by clinical contractors and cooperative groups under the direct supervision and support of DCT. Generally, drugs will remain in this category through Phase I and early Phase II studies in pertinent signal tumors before moving into Group B. A decision to move a drug into Group B will depend on the DCT staff's assessment of the completeness of the data obtained during these studies *and* on a decision not to drop the drug from clinical testing for drug safety or administrative reasons.

2. **Group B** drugs have gone beyond initial Phase II studies and have been deemed of clinical interest in the New Drug Liaison meetings and by DCT staff. Selected Group B drugs will be made available to investigators outside the DCT programs through the "New Drug Studies mechanism." This mechanism allows directors of comprehensive and clinical cancer centers, on a voluntary basis, to approve and to assume the responsibility for monitoring protocols from affiliated investigators. The decision whether to use this mechanism has been left to the discretion of each cancer center director (along with a determination of the geographical scope of affiliated investigators). The DCT is making plans to extend participation to other qualified cancer centers not yet invited to participate. Further information on the New Drug Studies mechanism is available from Dr. David Abraham, Investigational Drug Branch, CTEP, DCT, NCI; (301) 496-5223.

3. **Group C** drugs are available to qualified, registered investigators for specific disease indications under a guideline provided by DCT after approval by FDA. (They are also available for research protocol study.) These are drugs which have shown efficacy against a tumor type in more than one study, which alter the pattern of care of the disease in question, and which are safely administered by properly trained physicians without requiring specialized supportive care facilities. For example, this permits an investigator to receive cis-platinum for patients with nonseminomatous testicular cancer or recurrent ovarian cancer. FDA-approved guidelines for the use of these drugs are available from the Investigational Drug Branch. One responsibility implicit in using Group C drugs is further documentation of drug safety, and investigators are requested to report adverse drug reactions promptly. No other reporting is required.

These policies are more restrictive in accepting studies with certain drugs (Group A) but render other drugs more accessible for research study (Group B) or for clinical need (Group C). The assignment of drugs to each group is periodically revised and updated. Readers will be informed in this Newsletter of changes in drug classification. The current classification of drugs includes:

A. Group A Drugs

α-TGdR (NSC 71851)
Amino-thiadiazole (NSC 4728)
AMSA (NSC 249992)
Anguidine (NSC 141537)
Bruceantin (NSC 165563)
Chlorozotocin (NSC 178248)
3-Deazauridine (NSC 126849)
Dichloroallyl Lawsone (NSC 126771)
Dichloromethotrexate (NSC 29630)
Gallium Nitrate (NSC 15200)
Hycanthone (NSC 142982)
Maytansine (NSC 153858)
Misonidazole (NSC 261037D) (formerly Ro-07-0582)
Neocarzinostatin (NSC 157365)
Rubidazone (NSC 164011)

B. Group B Drugs

1. Drugs in Group B available through the New Drug Studies mechanism.

Baker's Antifol (NSC 139105)
β-TGdR* (NSC 71261)

Group B Drugs (con.)

Camptothecin (NSC 100880)
Cyclocytidine (NSC 145668)
Dianhydrogalactitol (NSC 132313)
Dibromodulcitol (NSC 104800)
Dibromomannitol (NSC 94100)
Diglycoaldehyde (NSC 118994)
Elliott's B Solution** (NSC V-7)
ICRF-159 (NSC 129943)
Melphalan (i.v.) (NSC 8806)
Methyl-GAG (NSC 32946)
Streptonigrin (NSC 45383)
TMCA (NSC 36354)
Tubercidin (NSC 56408)
VM-26 (NSC 122819)
VP 16-213 (NSC 141540)
Yoshi 864 (NSC 102627)

2. Group B drugs available *only* to DCT contractors and cooperative group studies:

Azaserine (NSC 742)
BCG - Connaught (NSC B116341)
BCG - Pasteur (NSC B116328)
BCG - Tice (NSC B116327)
Calcium Leucovorin (NSC 3590)
C-Parvum (NSC 220537)
Cycloleucine (NSC 1026)
~~DES†~~ (NSC 3070) not new—
Erwinia Asparaginase (NSC 106977)
Estradiol Mustard†† (NSC 112259E)
~~Fluoxymesterone† (NSC 12165E)~~ – not new—
Ftorafur (NSC 148958)
Isophosphamide (NSC 109724)
Levamisole (NSC 177023)
Mer-BCG (NSC 143769)
6-Mercaptopurine (i.v.) (NSC 755)
~~Methotrexate~~ (High Dose) (NSC 740) not new—
Phenestrine†† (NSC 104469)
Piperazinedione (NSC 135758)
~~Prednisolone† (NSC 9151E)~~ – not new—
~~Prednisone† (NSC 10023)~~ — not new—
Procarbazine (i.v.) (NSC 77213)
Pyrazofurin (NSC 143095)
Rifamycin SV†† (NSC 133100)

C. Group C Drugs

	Approved Indication
5-Azacytidine (NSC 102816)	Refractory AML
L-asparaginase (NSC 109229)	ALL

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*Because of a drug shortage, no new studies will be accepted for 3 months.
**Diluent.
†Special formulations.
††Not on inventory.

Group C Drugs (con.)

Daunomycin (NSC 82151)	AML and ALL
Streptozotocin (NSC 85998)	Islet cell carcinoma of the pancreas; carcinoid
MeCCNU (NSC 95441)	Carcinoma of the colon and stomach; melanoma
Hexamethylmelamine (NSC 13875)	Ovarian carcinoma
Cis-platinum (NSC 119875)	Nonseminomatous testicular carcinoma; refractory ovarian carcinoma

In summary:

Group A Drugs - limited to DCT-supported Phase I and early Phase II studies.

Group B Drugs - available for late Phase II (and beyond) studies by cooperative group members, DCT contractors, and for certain drugs, cancer-center-affiliated investigators.

Group C Drugs - available to physicians who meet the following requirements:

1. A physician must be registered with the National Cancer Institute as an investigator by having completed an FDA form 1573.

2. A written request for the drug must be submitted indicating the disease to be treated.

3. The use of the drugs shall be limited to indications outlined in the guidelines that will be provided to the investigator.

4. All adverse reactions must be reported to the Investigational Drug Branch.

For further information, please contact Dr. Vincent Bono, Chief, Investigational Drug Branch, Building 37, Room 6E-20, NCI, NIH, Bethesda, Maryland 20014; (301) 496-5223.

Ovarian Cancer Study

The members of the NCI contract-supported Ovarian Cancer Study Group are currently evaluating the optimal staging and therapy of Stage I and II epithelial ovarian carcinoma.

Surgical treatment by experienced investigators in the past has shown disappointing results with 5-year survival rates of 67 percent of the patients in Stage IA, 50 percent in Stage IB, and 43 percent in Stage IC. In a number of small nonrandomized studies in a selected group of patients, where either melphalan or intraperitoneal isotopes were administered following surgery, some beneficial effects have been noted. This improvement has never been demonstrated with precisely staged patients in a prospective, randomized clinical trial.

One question to be answered is the role of precise staging, including peritoneoscopy; peritoneal fluid cytology; and omental, pelvic, and subdiaphragmatic biopsies. The other goal is to determine the role of no further treatment v. melphalan in Stage IA and IB, and melphalan v. chromic phosphate in Stage IC and II.

If you are interested in the referral of such patients who are untreated with respect to radiation or chemotherapy and are within 2 months of their primary diagnosis, you are urged to contact the responsible investigator at the participating institution in your area:

- Mayo Clinic, Rochester, Minnesota - Dr. David Decker, (507) 282-2511
- M. D. Anderson Hospital, Houston, Texas - Dr. Ben Greer, (713) 792-2770
- Medicine Branch, National Institutes of Health - Dr. Robert Young, (301) 496-4916
- Roswell Park Memorial, Buffalo, New York - Dr. Joseph Barlow, (716) 845-5784 or Steven Piver, (716) 845-3110

If you desire further information concerning the protocol, please contact Dr. Alan Keller, Clinical Investigations Branch, National Cancer Institute, (301) 496-2522.

Correction About PALA

Several readers brought to our attention an error in *DCT Newsletter Number 3* (October 15, 1977). It was incorrectly stated that PALA (phosphonoacetyl-L-aspartate, NSC 224131) inhibits "the enzyme-catalyzing ring closure in *de novo* pyrimidine biosynthesis." PALA, in fact, inhibits the enzymatic synthesis of carbamyl aspartate (an open-chain compound), while the ring closure occurs in the next step in the pyrimidine biosynthetic pathway (the formation of dihydroorotic acid).

FDA NEWS

IND Submission

An IND for PALA (NSC 224131) was filed with the Food and Drug Administration on December 29, 1977. This is a high-priority drug in the DCT program, and it has been requested that the 30-day waiting period be waived by FDA to permit rapid initiation of Phase I clinical trials.

IND Approval

Two recent IND submissions have been approved by the Food and Drug Administration for:

1. Pyrazolo-Imidazole (NSC 51143), and
2. Indicine-n-oxide (NSC 132319).

These drugs will now enter clinical testing.

SPECIAL ANNOUNCEMENTS

Handling of BCG Vaccines

A question has arisen regarding the proper handling and disposal of the various BCG vaccines distributed by the National Cancer Institute (Connaught, Pasteur, Tice). In response to an inquiry to the Bureau of Biologics, the following recommendations were made:

1. Those individuals who work with BCG vaccines should exercise care to avoid contact with the products.
2. Discarded containers, syringes, and other equipment should be sterilized before disposal.

Since the concentrations used in immunotherapy are very high, usually 10^8 colony-forming units per ml or greater, even small droplets (which might be inhaled) can contain thousands of viable organisms. While the possibility of contracting BCG disease is remote, immunodeficient or immunosuppressed persons might be affected. Additionally, contact with the BCG vaccines may produce conversion to tuberculin reactivity and possible confusion as to the cause of the induced sensitivity.

Further information may be obtained by contacting the Pharmaceutical Resources Branch, Developmental Therapeutics Program, DCT, NCI, Blair Building, Room 428, 8300 Colesville Road, Silver Spring, Maryland 20910.

Readership Response

The response to our readership survey on updating and renewing the mailing list was overwhelmingly positive. We appreciate your continued interest and support in our efforts to promote rapid communication of information to participants in the DCT program.

DECISION NETWORK NEWS

Drug Development Decisions

At the last Decision Network meeting on November 30, 1977, the following actions were taken:

1. Passed Decision Network 2A (antitumor activity established in animal tumor models) -

   Aphidicolin (NSC 234714)
   Macromomycin (NSC D289642)

   Macromomycin (NSC 170105) has been renamed "Auromomycin." This compound contains chromophore and has been given a low priority.

2. Passed Decision Network 3 (toxicity established in animal models, ready for clinical testing) -

   Soluble ICRF Isomer (NSC 169780)
   PALA (NSC 224131)

3. Passed Decision Network 4 (Phase I clinical studies completed, ready for Phase II) -

   Hycanthone (NSC 142982)

Dr. Giovanella of The Stehlin Foundation for Cancer Research (Houston, Texas) presented *in vitro*[1] data that high concentrations of Thymidine (NSC 21548) are more toxic to neoplastic than non-neoplastic cells. *In vivo*[2] studies showed that 3g/kg/3 hours given s.c. for at least 72 hours arrested the growth of a human malignant melanoma in nude mice. No drug-related toxicity was seen. The Committee decided to explore supply requirements for future trials, perform confirmative screening tests, and look into toxicology requirements and assess available clinical experience with Thymidine to determine if additional data would be needed to expand clinical studies of high-dose thymidine.

DCT CALENDAR

Board of Scientific Counselors, DCT - March 13-14, 1978, Baltimore Cancer Research Center, Baltimore, Maryland.

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[1] Lee, S.S., and others. *J Cell Physiol*, 92:401, 1977

[2] Lee, S.S., and others. *Cancer Letters*, 3:205, 1977

[illegible]
Bulletin
October
1977

CANCER SURVIVAL AMONG WOMEN BY AGE

Cancer Diagnosed Among White Females, 1950-69

ALL STAGES OF DISEASE

Relative Survival Rate*

Age at Diagnosis	Stomach			Colon			Rectum			Lung and Bronchus		
	5 Years	10 Years	15 Years	5 Years	10 Years	15 Years	5 Years	10 Years	15 Years	5 Years	10 Years	15 Years
All Ages	13%	12%	†	45%	41%	41%	42%	37%	36%	12%	9%	†
45-54	14	†	†	47	42	36	46	39	36	13	†	†
55-64	13	†	†	47	48	46	47	41	36	12	8	†
65-74	13	11	†	46	46	38	30	22	31	16	†	†
75-84	13	13	†	30	30	48	32	37	†	6	†	†

Relative Survival Rate*

Age at Diagnosis	Breast			Uterine Cervix			Uterine Corpus			Ovary			Bladder		
	5 Years	10 Years	15 Years	5 Years	10 Years	15 Years	5 Years	10 Years	15 Years	5 Years	10 Years	15 Years	5 Years	10 Years	15 Years
All Ages	62%	49%	44%	58%	53%	50%	72%	68%	60%	31%	28%	27%	56%	52%	51%
45-54	62	51	46	67	61	47	83	80	76	33	29	26	66	63	†
55-64	60	47	39	54	47	42	73	67	66	27	22	28	60	53	46
65-74	61	48	39	49	40	39	61	54	50	21	17	†	53	44	†
75-84	58	46	51	37	32	†	47	48	†	19	18	†	43	38	†

LOCALIZED DISEASE

Relative Survival Rate*

Age at Diagnosis	Stomach			Colon			Rectum			Lung and Bronchus		
	5 Years	10 Years	15 Years	5 Years	10 Years	15 Years	5 Years	10 Years	15 Years	5 Years	10 Years	15 Years
All Ages	41%	37%	†	73%	67%	67%	66%	61%	59%	44%	35%	†
45-54	‡	‡	‡	76	68	61	73	60	†	‡	‡	‡
55-64	‡	‡	‡	74	68	†	72	64	60	‡	‡	‡
65-74	41	36	†	72	63	63	62	64	62	‡	‡	‡
75-84	‡	‡	‡	65	65	†	64	59	†	‡	‡	‡

Relative Survival Rate*

Age at Diagnosis	Breast			Uterine Cervix			Uterine Corpus			Ovary			Bladder		
	5 Years	10 Years	15 Years	5 Years	10 Years	15 Years	5 Years	10 Years	15 Years	5 Years	10 Years	15 Years	5 Years	10 Years	15 Years
All Ages	84%	74%	69%	77%	73%	70%	84%	80%	85%	73%	67%	65%	71%	66%	66%
45-54	85	76	70	77	71	67	91	86	87	71	68	61	‡	‡	‡
55-64	84	75	64	74	65	62	84	75	77	67	60	†	78	67	81
65-74	82	67	62	73	61	60	76	69	68	60	56	†	67	59	†
75-84	82	75	81	‡	‡	‡	80	80	†	‡	‡	‡	80	56	†

*Relative survival rate is the observed proportion surviving among the cancer patients under consideration divided by the proportion expected to survive in the general population with the same age distribution, based on population mortality rates during the period under observation.

†Fewer than five deaths from cancer.

‡Fewer than 400 cases diagnosed.

Source of basic data: Unpublished data from End Results Evaluation Program, National Cancer Institute, Bethesda, Maryland.

APPROPRIATIONS IN THOUSANDS
TO NCI AND TO NIH

YEAR	NCI	NIH	RATIO OF NCI TO NIH
1938	400	464	86%
1939	400	464	86%
1940	570	707	81%
1941	570	711	80%
1942	565	700	81%
1943	535	1278	42%
1944	530	2555	21%
1945	561	2835	20%
1946	549	3415	16%
1947	1821	8076	23%
1948	14,500	28,876	50%
1949	14,000	37,668	37%
1950	18,900	52,146	36%
1951	20,000	60,060	33%
1952	20,000	57,676	35%
1953	18,000	59,031	30%
1954	20,000	71,153	28%
1955	22,000	81,268	27%
1956	25,000	98,458	25%
1957	48,000	213,000	23%
1958	56,000	241,000	23%

YEAR	NCI	NIH	RATIO OF NCI TO NIH
1959	75,000	324,000	23%
1960	91,000	430,000	21%
1961	110,000	577,000	19%
1962	143,000	767,000	19%
1963	156,000	931,000	17%
1964	143,000	974,000	15%
1965	150,000	1,059,000	14%
1966	164,000	1,244,000	13%
1967	176,000	1,413,000	12%
1968	183,000	1,179,000	16%
1969	185,000	1,394,000	13%
1970	190,000	1,523,000	12%
1971	233,000	1,654,000	14%
1972	379,000	2,190,000	17%
1973	492,000	2,497,000	20%
1974	551,000	1,852,000	30%
1975	670,000	1,934,000	35%
1976	745,000	2,124,000	35%
1977	815,000	2,404,000	34%
1978	867,000	2,551,000	34%

APPROPRIATIONS IN THOUSANDS TO INSTITUTES IN NIH OTHER THAN NCI AND NIMH

YEAR	HEART & LUNG	DENTAL	ARTH.	NEUROL.	ALLERGY & INFEC.	GEN. MED. SCI.	CHILD HEALTH	AGING	EYE	ENVIR. HEALTH SERV.	TOTAL	NOTES
1965	125	20	113	88	70	104*	43	-0-	-0-	-0-	563	*General Medical Science included in GRS-NIH.
1971	195	35	138	104	102	160	95	-0-	30	20	879*	*56% increase in six years.
1977	397	56	209	156	141	205	146	30	64	49	1,453*	*65% increase in six years.
1978	446	61	258	177	161	230	165	37	85	64	1,684	91½% increase since 1971

RESEARCH
EDUCATION
CONTROL
P.O. BOX 2370 RESTON, VIRGINIA TELEPHONE 703-620-4646

THE 66 SUSPECTED CASES OF WANTON OR UNNECESSARY SURGERY DOWN TO THREE

Now it turns out that the infamous 66 Breast Cancer Detection Demonstration Project cases in which women supposedly were duped into having mastectomies although their tumors were benign are really only three–if that.

The 66 suspected cases were found by pathologists reviewing 506 cases of minimal cancer–one centimeter or less–of the 2,487 cancers detected so far in the project. This review was conducted by the Beahrs Working Group under its contract with NCI to take a hard look at the project, especially the mammography aspects. The pathology review was conducted hastily so that it would be ready for the consensus meeting last September, when a panel of scientists and lay persons was convened to develop recommendations for the project's operation.

The Beahrs report noted that the pathology review had found 66 cases in which the working group pathologists, looking only at the slides and without access to any other information about the cases, had determined the tumors were not malignant.

Although Oliver Beahrs, head of general surgery at the Mayo Clinic, cautioned that this was a preliminary report and needed further study, critics such as the Nader organization picked it up and rushed out to damn NCI, American Cancer Society and the medical profession in general.

After the consensus meeting, Beahrs put his group back to work re-reviewing the 66 cases. The final report will be released next month; here is what it will say, Beahrs told the Cancer Control & Rehabilitation Advisory Committee:

–Of the 66 cases, two were in the group's first report because of computer error. That cut to 64 the number of cases in which women were treated for breast cancer although their tumors were thought, in the first review, to be benign.

–The group obtained additional, representative slides on 38 of the cases. "Why didn't we get them originally?" Beahrs commented. "Because of time constraints." Also, some slides were not considered because they were not of the original biopsies but of breast tissue after the breast was removed.

In reviewing these additional 38 cases, the Beahrs pathologists agreed that 16 were malignant, after all. That reduced the number of questionable cases to 48.

–Of those 48, the patients' physicians in 11 cases decided that since they were borderline lesions, they would not treat by mastectomy. So 11 of the 66 original suspected cases did not have their breasts removed.

–That reduced to 37 the number of cases in which mastectomies were performed, "recklessly and unnecessarily," the critics charged. However, of those 37, the two stage procedure was followed in 30 cases. This involved biopsy, followed from one day to seven months later, by mastectomy. Presumably during the intervals, pathologists, treating physicians and patients carefully considered the benign vs. malignant issue and treatment alternatives.

–Of the 30 choosing mastectomies, there was concurrence by hospital and project pathologists in the diagnosis in 25 cases. Outside pathologists were consulted in 15 cases, and almost all considered the lesions malignant, Beahrs said. Fifteen of the 30 had simple mastectomies, 14 modified radical and one radical.

–Of the seven cases in which biopsies were followed immediately by mastectomies, BCDDP pathologists agreed with the hospital pathologists that the lesions were malignant in two instances. Slides were not available in two others.

Project pathologists were in disagreement with the hospital pathologists in the remaining three cases–that is, the hospital pathologists determined after biopsy that the tumors were cancers and mastectomies were performed immediately; and project pathologists later said they were benign. Thus, those three were the only apparent cases in which women underwent treatment that may not have been necessary without carefully considering the issues and alternatives.

There are those who will contend that even three is too many, out of 506, and they are probably right. But the final resolution of the 66 cases demonstrates that the earlier polemics were not justified.

DCCR Director Diane Fink pointed out that BCDDP is turning up a large number of the small lesions, compared with data in the NCI SEER study and the HIP study in New York.

"The Beahrs review tends to dissipate the charges that the project has led to a alot of unnecessary surgery," commented advisory committee member Saul Gusberg. "That's not the main issue. The main issue is whether or not mammography is the alleged hazard." Gusberg noted that women are being screened in the projects with as little as .2 rad, and that the average is now down to .5 rad.

"When they say it is a question of benefit vs. a presumed risk, they should say questionable risk," Gusberg said. "Physical examination does not have the capacity to determine lesions to the same degree of accuracy as mammography. I wonder if we're not neglecting the 40-50 age group (which receives mammography in BCDDP only if they have a personal or familial history of breast cancer), where we could possibly find early lesions and employ more conservative surgery."

Committee member Sam Shapiro said, "There is a strong consensus that there is a risk, although the question of magnitude of risk remains. It was concluded (by the consensus panel and others) that there is no scientific evidence of benefit to the group under age 50. The consensus report said that NCI should give high priority to research on the use of mammography as a screening technique for women under age 50."

"We do have the nugget, that there is a positive benefit for women over 50, as a screening package, including mammography and physical examination. Women over 50 should be aware that there is a benefit."

PART II

AN OPPORTUNITY FOR CANCER PREVENTION

Chemical carcinogenesis, the production of cancer by chemicals, is part of a larger problem of the hazards facing man in today's environment. Ecologists, who specialize in study of the mutual relations between living things and their external surroundings, have warned that man is jeopardizing his very survival by continuing to pollute his environment at an accelerating rate.

There are dangers in addition to that of the extensive illness caused by loading the atmosphere with enormous quantities of pollutants. The thin envelope of air, water, and soil that sustains all earthly creatures may be changing and, ultimately, the ability of the earth to support life may be destroyed. Blocking of vital cycles that link atmospheric elements and living organisms is a possibility, ecologists say.

The oxygen cycle, for one, may be affected. Oxygen is produced by green plants by the process of photosynthesis and some 70 per-

Pollution of the environment with automobile exhausts, factory wastes, pesticides, and other potentially harmful substances is interfering with the biological balance of nature and is increasing at an accelerated rate.

cent of the earth's annual supply is produced by certain minute ocean plants. Only a very small fraction of the hundreds of thousands of man-made substances, biological wastes and other pollutants, that have been added to the environment has been tested for toxicity to these marine diatoms. There is some evidence, for example, that the insecticide DDT can suppress photosynthesis in bodies of water. One ecologist recently made an estimate of the oxygen balance within the borders of the United States. He found that the amount of oxygen produced was not quite 60 percent of the amount consumed, and concluded that this country is absolutely dependent on oxygen produced outside its borders, mostly in the Pacific Ocean, and brought in by atmospheric circulation.

This is only one illustration of the broad concerns of experts in many fields, such as ecology, medicine, and geophysics, for the kinds of changes that man is creating in his environment. In the main, the concerns derive from two major trends—mushrooming spread of pollution and the so-called population explosion, which is partly responsible for increasing pollution. Estimates suggest that 400 to 500 new chemicals are added each year to the half-million already in the environment; and that the world population, which during the summer of 1968 passed the 3.5 billion mark, will double in 35 years if present rates should continue.

Recognition that man's relation to his environment is one of the most important problems facing society today has resulted in intensified efforts by many groups, both within and outside government, to achieve better understanding of the nationwide and global consequences of pollution. With such information at hand, successful methods of preventing great and perhaps irreversible damage to the environment can be devised.

A major development was the enactment of the Air Quality Act of 1967, administered by the Department of Health, Education, and Welfare, calling for a coordinated attack on air pollution on a regional basis. Under the act, the Department has designated air quality control regions in metropolitan areas, and the States and the District of Columbia are required to adopt and enforce air pollution standards based on criteria for air quality issued by the Department. Criteria for sulfur oxides and particulates (solid or liquid pollutants) have been issued recently. The act also authorizes national standards for motor vehicle emissions, activities in support of State and local agencies for control of stationary sources of pollution, and continuation of surveillance and data gathering activities.

On May 29, 1969, the President announced the establishment of an Environmental Quality Council and a Citizen's Advisory Committee on Environmental Quality, whose functions are to advise him on environmental quality matters. The Council is chaired by the President, and consists of the Vice President; Secretary of Agriculture; Secretary of Commerce; Secretary of Health, Education, and Welfare; Secretary of Housing and Urban

Mr. ROGERS. Thank you very much, Dr. Byrd, for a very excellent statement, and for giving us an update on what is happening in the cancer field.

Dr. Carter?

Mr. CARTER. Thank you, Mr. Chairman.

You feel that a second opinion is necessary before forcing patients in nonsurgical treatment for cancer?

Dr. BYRD. Dr. Carter, I have grave doubts about the second opinion as a general program, because it forces the patient into doctor shopping, which is reasonably futile. I have suggested to the patients in my own experience that they find someone in whom they have confidence, and not try to decide for themselves what type of treatment they want. This is a little apart from what you are speaking about.

I don't know how we will ever satisfactorily work out a second opinion program of a major caliber.

Mr. CARTER. I see.

Will therapeutic chemotherapy alternatives in some cases, actually cause additional cancer?

Dr. BYRD. Yes. I don't think that there is any doubt about that. Many of the agents that are used, in managing cancer patients, are in themselves carcinogenic. We are seeing now, the figures are off the top of my head, that the survivors of one childhood cancer who have been treated with chemotherapy, are now at a period of 5 to 10 years beginning to show up with second cancers. So we have this constant problem that we are dealing with, very difficult and dangerous agents, and their use must be well defined.

The study which I am referring to began at 5 years, and was for 5 years on.

Mr. CARTER. If you have a cancer of the body of the uterus, there is metastasis to the lymph nodes adjacent to the area of the fallopian tubes, for example, would you advise that patient to have X-ray therapy or chemotherapy before surgery?

Dr. BYRD. Dr. Carter, I am not a gynocologist, but, of course, one of the great benefits that is coming out of the National Institute's program is its concept of cancer as a multidisciplinary problem. Yes; I would suggest that such a patient have radiation therapy prior to any surgical procedure.

Mr. CARTER. It might be susceptible to chemotherapeutic agents, and you might even use that.

Dr. BYRD. It is certainly not beyond the realm of possibility.

Mr. CARTER. Let me congratulate you on the work that you have done. Thank you so much.

Mr. ROGERS. Mr. Maguire wanted to ask; do you agree with the current feeling that a great many cancers are caused by environmental factors, and are, therefore, preventible?

The second part of it is; would it not follow that more effort should be put on prevention by the NCI and the ACS?

Dr. BYRD. Mr. Chairman, the general concept of environmental cancer is based on a worldwide experience. I am getting a little philosophic, so forgive me. There is a worldwide incidence of cancer of all types. As you know, this varies between our country and others.

We have more in some instances, and less in some others. This difference is thought to be environmental for one reason or another.

If this is true, then something like 80 percent of all cancers are environmental in origin. We are doing a great deal about some types of cancer, as far as our study, as far as our dedication. I feel that this is a particularly fruitful area for study by the National Cancer Institute, and the American Cancer Society has made dedicated efforts towards it.

Mr. **Rogers**. Thank you.

What about the comprehensive cancer centers, do you think that they are currently an important part of the cancer program, and are they doing their job well?

Dr. **Byrd**. I think that your committee will hear a great deal about these things. I think that they are an essential part of the cancer program of the United States for the research that they are doing, but so much more for the training process that they are involved in.

Mr. **Rogers**. It has been proposed that basic research along with the clinical research should be included in the core grants to the centers. Would you think that this is a good idea?

Dr. **Byrd**. One comes constantly into the difference between basic research and oriented research.There is a great need for basic research into cancer problems, but this may be subdivided in itself.

I think in many instances the cancer centers have this basic capability, and the capability of carrying research on into clinical experience, and the ability of those with clinical experience to counsel with the basic investigators in the early stages of their study, which gives them a unique role.

Mr. **Rogers**. Should we include as members of the Cancer Advisory Board individuals who are experts in environmentally caused cancer?

Dr. **Byrd**. Very definitely. We need people with that capability. Dr. Bruce Ames is on the board.

Mr. **Rogers**. Thank you so much. We are very grateful to you for being here.

The subcommittee stands adjourned, to reconvene at 10 o'clock tomorrow morning.

[Whereupon, at 5:05 p.m., the subcommittee adjourned, to reconvene at 10 a.m., Thursday, March 2, 1978.]

BIOMEDICAL RESEARCH AND RESEARCH TRAINING AMENDMENTS OF 1978

THURSDAY, MARCH 2, 1978

House of Representatives,
Subcommittee on Health and the Environment,
Committee on Interstate and Foreign Commerce,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:25 a.m. in room 2322, Rayburn House Office Building, Hon. Paul G. Rogers, chairman, presiding.

Mr. Rogers. The subcommittee will come to order, please.

We are beginning our second series of 3 days of hearings on H.R. 10908, H.R. 10190, and all similar bills to revise and extend biomedical research and research training authorities which expire on September 30, 1978.

Today the subcommittee will hear from several panels of distinguished individuals and organizations. So, we are very pleased to have our witnesses here today, and we would ask Dr. Edwin H. Lenette, chief, Biomedical Laboratories and president-elect of the American Society of Microbiology to take the stand. He is, I believe, accompanied by Dr. Cox, who is chairman of the Public Affairs Committee.

We welcome you gentlemen to the committee. Your statement will be made a part of the record in full, and you may proceed as you desire.

STATEMENT OF EDWIN H. LENNETTE, M.D., PH. D., PRESIDENT-ELECT, AMERICAN SOCIETY OF MICROBIOLOGY, ACCOMPANIED BY C. D. COX, PH. D., CHAIRMAN, PUBLIC AFFAIRS COMMITTEE

Dr. Lennette. Mr. Chairman, thank you for the opportunity to discuss our assessment of the H.R. 10908 bill, the Biomedical and Research Training Amendments of 1978.

I am speaking as president-elect of the American Society for Microbiology and I have with me today Dr. C. D. Cox, who is chairman of our Public Affairs Committee. The American Society for Microbiology is composed of over 27,000 members who contribute to the applied fields of infectious diseases, clinical microbiology, industrial fermentation processes, ecological microbiology and food technology, as well as the fundamental areas of immunology, pathology, genetics, virology, oncology, microbial physiology, environmental microbiology, mycology, and host parasite interactions.

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As chief of the biomedical laboratories of the California Department of Health, I have had to deal with many issues involving both of the Institutes mentioned in this bill, and with problems involving postdoctoral training under the NRSA program. I should also like to express my appreciation for the opportunity provided the Public Affairs Committee of the American Society for Microbiology to work in the past with this and with other congressional committees on biomedical research issues, and to assure you that our interests in the subject of biomedical research are both broad and abiding. I mention this with specific emphasis lest anyone feel that our recent activities in recombinant DNA legislation may represent our only major concern.

Let me begin by stating that we generally agree with the 3-year extension of the authorizations for the National Heart, Lung, and Blood Institute and the National Cancer Institute at the indicated dollar figures. We are interested in seeing an indepth review of the biomedical research activities of the National Institutes of Health, and we recognize the inability to accomplish an adequate review in a period of 1 year. Therefore, we favor in general the 3-year extension period.

We also agree in general with section 302 of title III, inasmuch as we favor the return of the National Cancer Institute to normal status as one of the National Institutes of Health. We would also favor the return of NCI to the normal NIH budgetary process.

We strongly favor section 401 in title IV in extending authorization levels for the National Research Service Awards at the recommended dollar figures. We are particularly pleased with section 402, which would provide that the Secretary of HEW determine the subject areas in which awards would be made, after taking into consideration the most recent results of the NAS study of research personnel needs.

We have commented at length concerning the NAS manpower report and especially on deficiencies regarding our own Society and science. As stated earlier, the American Society for Microbiology enjoys a membership of over 27,000 microbiologists with about half holding the doctoral degree, and about half holding bachelors or masters degrees. The latter two categories were not covered in the 1976 NAS report, nor are they covered in the 1977 report. We continue to believe that the absence of these data is a serious omission because of the inability to predict future needs without knowledge of the manpower pool which feeds predoctoral and postdoctoral programs.

We should not base our recommendations for training funds for the next 10 years solely upon existing market demands, when 6 to 10 years training after college is required to complete the training of competent biomedical scientists. The NAS committee's 1977 report recommends that predoctoral research awards be reduced to 4,250 by fiscal year 1979, a decrease of 20 percent from fiscal year 1976.

Further, the report asks that support in predoctoral research training be given broadly among the basic medical sciences. The deliberate cutting back of predoctoral research will have a deleterious effect on medical microbiology, and indeed most of the basic biomedical sciences, and many cause irreparable harm by depleting a manpower pool which has traditionally supplied postdoctoral manpower markets.

For several years we have been hearing a great deal about the on-again off-again support of basic research and of basic research training of scientists. The same spigot effect when practiced in traineeships and fellowships is equally harmful.

Applying the skills necessary to conduct research in complex scientific disciplines requires a minimum of 6 years of on-the-job training—approximately 4 years of predoctoral and 2 years of postdoctoral training. In our experience, young people of the caliber sufficient to perform productively will not enter a field in which remuneration is markedly less than in other professions unless they are supplemented financially during their training. We therefore strongly urge the implementation of a stable research training program that would permit support of young scientists in numbers adequate to meet the future health needs of this country. We disagree that the present level of support for research training is sufficient, and we contend that current funds for research and research training are inadequate.

Therefore, it makes a great deal of sense to us that the Secretary of HEW should have the authority to determine the subject areas in which the awards shall be made after giving due consideration to the most recent results of the NAS and other studies.

We do have a philosophical problem with section 472(b)(4) in that we think it is educationally unwise to encourage a 5-year term for predoctoral study. We realize that the average length of predoctoral training may be 5 years or slightly more; nevertheless, we question the philosophy of encouraging this length of predoctoral training. However, from a practical point of view, we feel that this is an educational problem and that under the present situation we would concur with this section.

We agree in principle with sections 472(b)(4), section 404, and section 405; however, there are two or three items which deserve additional comments.

One. On September 6, 1977, the Internal Revenue Service issued a formal ruling which held that all research training stipends paid under the National Research Service Awards Act of 1974 were and are fully taxable—awards received by trainees after June 1, 1974. The IRS ruling applied only to taxes on research training awards made under the NRSA Act by NIH and ADAMHA and not to awards made under other authorities or by private agencies. In the past, recipients of research training stipends who were doctoral degree candidates had been allowed to exclude their awards from taxable income. Postdoctoral recipients have been permitted to exclude up to $300 per month to a maximum of 36 months. The initial assumption had been that the 1974 act did not alter this situation. However, the 1974 act includes a "pay-back" provision and the IRS, in its September 1977 ruling, held that the "pay-back" makes the awards fully taxable, retroactive to 1974.

The Association of American Medical Colleges believes the IRS reasoning is faulty and has sought—though without success—to obtain a reversal of the ruling, working with other academic organizations and through its attorneys to effectuate this end. Our Public Affairs Committee is supportive of their efforts and is working in concert with them.

Having failed to achieve a reversal we are now seeking to have the NRSAs included as part of the comprehensive study of scholarships authorized under the 1976 Tax Reform Act. A study is being conducted by the staff of the Joint Committee on Taxation to assist Congress in developing a uniform policy for all such aid programs. Pending completion of this study and further Congressional action, scholarship programs included in the study are exempt from taxation as before.

We have just been informed that Senator Gaylord Nelson, Democrat, Wisconsin, has recently provided an amendment for an appropriate tax measure. We applaud such action and urge that other congressional committees and their staffs support this effort.

Two: We are particularly concerned that language of this bill take into account first those predoctoral candidates who do not complete the full predoctoral training for reasons which are beyond their control, and second, the short-term training programs—such as summer programs at Woods Hole—and short-term training programs in pathology, genetics, and so forth. In both situations these individuals should be exempt from the pay-back requirement.

Three: Section 503 deserves a brief comment. We are in agreement that authority should be provided for the director of NIH to appoint experts and consultants for his use and for use by all institutes except those which already have authority to do so, but we question somewhat the 2.5-percent limit of the number of current employees of NIH imposed on the number of such experts and consultants.

A separate concern is that we see no provision for any significant change in the number of study sections for evaluation of research grants proposals, and these study sections are greatly overworked. We suggest that consideration by given to providing for increased help on the study sections for research grant reviews. Finally,

Four: We also understand that the law mandates that the interest which must be paid back shall be at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the U.S. Government becomes entitled to repayment. It would seem far more reasonable and equitable to impose the current interest rate for educational loans, than the higher private consumer interest rate which is currently 13.5 percent.

Thank you, sir.

Mr. ROGERS. Thank you, Dr. Lennette. I think the suggestions you have made have much merit, and we will carefully check into them. Thank you for your testimony and for being here.

Dr. Carter?

Mr. CARTER. Thank you, Mr. Chairman.

Doctor, I find myself in agreement with what you have to say, I believe, all the way through. I do not think we should cut your funding down. If we are going to really go forward in research we have to fund more projects than the 4,250 which you mentioned, as I see it.

I notice that you have mentioned we should follow the National Academy of Science, or rather the Secretary should follow their recommendations; is that correct?

Dr. **Lennette.** And others, yes, sir.

Mr. **Carter.** All right, sir. I was interested about the research training stipends being taxed, and that they would be considered taxable retroactive to 1974; is that correct?

Dr. **Lennette.** That is the current interpretation from IRS.

Mr. **Carter.** How much do these stipends usually amount to?

Dr. **Lennette.** Could you answer it?

Mr. **Cox.** They are usually about $3,600 on the predoctoral, and about $10,000 to $11.000 on the postdoctoral.

Mr. **Carter.** $3,600 for——

Mr. **Cox.** Predoctoral.

Mr. **Carter.** Well, the oversight, I suppose, was not brought to our attention, but we did pass legislation to exempt those under the Berry plan and also the National Health Corps. I believe as the prime sponsor of that legislation, Mr. Chairman, in the House, I regret we did not include you. Certainly, I think you should have been included. That was partly my fault and partly the fault of all of us.

But I certainly support you strongly, and I will do everything I can to see that you have what you need to advance the cause of science and knowledge in this area.

Thank you, Mr. Chairman.

Dr. **Lennette.** Thank you very much, sir.

Mr. **Rogers.** Mr. Walgren?

Mr. **Walgren.** No questions, thank you.

Mr. **Rogers.** Did you have anything, Dr. Cox?

Has the tax problem been a deterrent, do you think, in getting people to come into the program?

Dr. **Lennette.** In the small postdoctoral training program that I have, if it is retroactive, it will cause some problems. Since the ruling came out we have had no new applicants, but there has been some inquiry as to how that would affect their stipends.

Certainly, on $3,600, that is a pittance. In this day, with the postdoctoral students at the age at which they come in, with family responsibilities, $10,000 or $11,000 does not go too far.

Mr. **Rogers.** No; I am sure of that.

Mr. **Carter.** Mr. Chairman, if you would yield on that?

Mr. **Rogers.** Certainly.

Mr. **Carter.** That causes a great problem to the military services and also to the National Health Service Corps, that tax deal.

Mr. **Rogers.** I think it was given under the assumption it would not be taxed, and then the IRS made a ruling. Now, has that been challenged in court yet?

Dr. **Lennette.** No, sir.

Mr. **Rogers.** Not yet. All right. Now, should the awards be institutional, or individual?

Dr. **Lennette.** I think the next panel's testimony may be to that effect.

Mr. **Rogers.** All right, we will take that up with them.

Mr. **Cox.** If I could say something on that.

Mr. ROGERS. Certainly.

Mr. COX. I think the ASM position on this would be that obviously we are in favor of institutional awards, but we feel strongly that the individual fellowship should be available because there may be institutions that are not capable, for various reasons——

Mr. ROGERS. In other words, you feel there should be a mix.

Mr. COX. Yes, very definitely.

Mr. ROGERS. Thank you.

Mr. CARTER. Mr. Chairman?

Mr. ROGERS. Yes, Dr. Carter.

Mr. CARTER. What areas of basic research look especially promising at this point?

Dr. LENNETTE. I find that difficult to answer because there is such a large field and so many different interests. Certainly, the basic areas of cancer research and molecular biology aspects are highly important.

Mr. CARTER. Cancer research?

Dr. LENNETTE. Cancer research, the basic aspects of cancer research.

Mr. CARTER. Yes, sir.

Dr. LENNETTE. And I was thinking of some of the programs which had to be cut back because of lack of funds.

Mr. CARTER. Yes, sir. It looks like we would cut some place else. Do you feel that financial support is needed to assure adequate numbers of personnel with training at the bachelors and masters degree levels?

Dr. LENNETTE. Do I feel?

Mr. CARTER. Do you feel that financial support is needed to assure adequate numbers of personnel with training at the batchelors and masters levels?

Dr. LENNETTE. I will let Dr. Cox answer that.

Dr. COX. This is a very difficult question to answer because, as we stated, we do not have good figures on this. The NAS report on manpower has figures for the Ph. D. and the M.D. levels, but they have not included batchelors and masters degree people who feed the predoctoral and postdoctoral programs. So, really, we do not have good information on that.

I would say that I think the most important thing is predoctoral and postdoctoral support. But that is really a negative answer because I do not have good figures on the batchelors and masters, the manpower figures, in our own field.

Mr. CARTER. To which would you devote the most funds, predoctoral or postdoctoral?

Dr. COX. Well, most funds are the number. It takes about three times as much to support a postdoctoral—three or four times—than it does a predoctoral. Microbiology being a multidisciplinary field, and we are into so many subdisciplines, some of these subdisciplines are in greater demand than others. But I think that it is too bad to cut out predoctoral support. There are no predoctoral training grants, no predoctoral support programs today, and I think that is a great disservice.

I still would primarily support postdoctoral, but I think we should have predoctoral support as well.

Mr. Carter. Mr. Chairman, let us look at this. We cannot afford to let these programs go down.

Mr. Rogers. Well, as a matter of fact, we authorized predoctoral programs, but they have never been carried out with the intent of the law.

Mr. Carter. The funding right now, really, we have cut it back this year, have we not? All of them are recommending a minimum of $540 million, and actually our authorization is less than that.

Mr. Rogers. I am not sure.

Mr. Dalrymple. The proposed authorization level in H.R. 10908 is $220 million for fiscal 1979, $240 million for fiscal 1980, and $260 million for fiscal 1981.

Mr. Rogers. Who is recommending half a billion?

Mr. Dalrymple. I do not know if anyone is recommending that. I think that is the total for the 3 years.

Mr. Carter. If you would give us these again, please.

Mr. Dalrymple. $220 million for fiscal 1979.

Mr. Carter. $240 and $260 million.

Mr. Rogers. So, we tried to increase it, and we will look at that figure, I agree.

Mr. Maguire?

Mr. Maguire. I have no questions, Mr. Chairman.

Mr. Rogers. We do have some questions we would like you to answer for the record, if you do not mind. Thank you for being here, we are grateful.

Our next witness is Dr. Lowell Greenbaum, who is professor of pharmacology, Columbia University, College of Physicians and Surgeons, on behalf of the Federation of American Societies for Experimental Biology, accompanied by Dr. Brian A. Curtis, who is associate professor of physiology, Peoria School of Medicine.

We welcome each of you, and the committee expresses its appreciation for your presence here today. Your statement will be made part of the record without objection, and you may proceed.

STATEMENTS OF LOWELL M. GREENBAUM, PH. D., CHAIRMAN PUBLIC AFFAIRS COMMITTEE, FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY; AND BRIAN A. CURTIS, PH. D., MEMBER

Dr. Greenbaum. Thank you, Mr. Rogers, it is a great personal pleasure to meet you once again, we certainly had much testimony together.

My name is Lowell Greenbaum, I am professor of pharmacology at the College of Physicians and Surgeons, Columbia University. Additionally, I am director of the medical scientist training program at Columbia, and director of graduate studies in the Department of Pharmacology.

I appear before you today as chairman of the Public Affairs Committee of the Federation of American Societies for Experimental Biology. The federation is comprised of six learned societies representing basic research disciplines in biomedical sciences. The societies have a combined membership of about 17,000 at the doctorate level.

I am accompanied by Dr. Brian Curtis, assistant dean of medical education and associate professor of physiology at the Peoria School of Medicine. Dr. Curtis is also a member of the FASEB Public Affairs Committee.

I have a relatively short statement to make, and then Dr. Curtis and I shall be happy to respond to any questions.

Before addressing the subject of this hearing and the substance of H.R. 10908 and related bills, may I say how much we appreciate and welcome the opportunity you have provided for the public to participate in deliberations on this legislation.

Having said that, the first thing I would like to say about H.R. 10908 is that we are very happy to see it. We are pleased to see the 3-year extension of legislative authorities for the several institutes and programs, and we are pleased to see the authorized funding levels. The bill gives the biomedical research enterprise two things it needs and has not had in some time—a sence of support, and a sense of stability.

If I may take the titles of the bill out of order, I would like to go first to title IV because it best illustrates the point I am making. The National Research Service Awards program fills a unique and important national need that cannot be met in any other way. It is a program to help a specially qualified group with the potential for putting all of mankind in their debt through basic research training, which will eventually lead to the prevention, detection, treatment, and possibly elimination of disease.

Yet, in spite of the self-evident need for this program to serve the common good, it has been under persistent attack from various quarters of the Government and has suffered under what you, Mr. Chairman, have described as: "The uncertainties and disruptions of the program under the previous two administrations." Most recently the program has been afflicted with the ruling of the Internal Revenue Service which declares these modest stipends, which are at $3,900, susceptible to full income tax because of the payback provisions of the law. This latest injury may be an unintended accident of lawmaking, as Dr. Carter has mentioned, but it is nonetheless real and painful. This program has been in trouble with the Government and, as a training program director, I can foresee trouble brewing with those it is designed to attract and enlist in the service to the country.

Mr. Chairman, I believe the bill you have introduced will go a long way toward turning this situation around. The 3-year extension of authority for the program and the authorized levels of funding spell stability and support. That is good news indeed. But an equally important form of support is found in the various amendments you have proposed to the authority for this program. We endorse all of those amendments.

I would now like to offer a few suggestions concerning title IV, for consideration by the committee.

We support the periodic adjustment of stipends of the trainees to reflect cost-of-living increases. We further recommend that postdoctoral stipends be brought to levels that are commensurate with those in medical residency training. This would mean something in the order of about a $3,000 increase over what they are now.

On the subject of payback, we agree that the amended recommendations are equitable. We would suggest, however, that trainees who do not complete more than 1 year of training should not be held to payback. They are not qualified to carry out research or teaching service. The elimination of the payback for those studying for less than 1 year would also, as Dr. Lennette has mentioned, permit short-term intensive research training programs at our research centers, such as Woods Hole, Mass., Cold Spring Harbor, (N.Y.) et cetera. It would allow funding under the NRSA program to be made to them without requiring payback for the students who participate in those programs.

We are in accord that there be a complete study of biomedical and behavioral research personnel by the National Academy of Sciences every 3 years rather than every year. But we recommend the study be divided into three parts, with one part being completed and reported each year. This would permit more thorough study and would preclude the need to develop a new staff every 3 years.

We are in accord—again going back to title IV—we are in accord that there be a complete study of biomedical and behavioral research personnel by the National Academy of Sciences every 3 years, rather than every year. But we recommend that the study be divided into three parts, with one part being completed and reported each year. This would permit more thorough study and would preclude the need to develop a new staff every 3 years.

Mr. Chairman, we urge you to further amend the legislation to remove the necessity of council action for individual postdoctoral fellowships. This would speed up the procedure of award by three or four months and make it more practical.

Mr. Chairman, I would like permission to introduce Dr. Curtis at this point to complete our testimony for his comments on the titles of the bill.

Mr. Rogers. Dr. Curtis?

STATEMENT OF BRIAN A. CURTIS, PH. D.

Dr. Curtis. Mr. Chairman, we wholeheartedly support the provisions of title I, relating to the National Library of Medicine. In particular, we endorse the appointments to the Board of Regents by the Secretary. The Library has done and is doing a splendid job of carrying out an indispensable and expanding mission for all of us.

With respect to title II, we would only reemphasize the importance we attach to the 3-year extension of legislative authority proposed for the National Heart, Lung, and Blood Institute.

We would strongly suggest that the report accompanying the bill might include language to encourage the Institute to continue its superb record of stimulating investigator-initiated research into basic research areas. It was noted in a recent study supported by that Institute, by Comroe and Dripps, of 10 major clinical advances—which included open heart surgery, cardiac pacemakers, cardiac-pulmonary resuscitation—they found that almost half of the research which they felt was crucial to the development of these clinical techniques was classified as basic research, did not set out to solve any one of these particular problems. Several of the key advances came, really, as unforeseen outcomes of quite unrelated basic research.

We note with some concern the mandate—as we read it—for all centers to expand their activities to include educational programs for health professionals as well as the public. We worry that the essential research mission of at least some centers may be compromised by spreading the talent they contain just a little bit too thinly. We would recommend that the slightly more permissive language in respect to education embodied in title III—that is in the Cancer Institute—you extend the ability to mount educational programs; but as we read it, it is not mandated. We would urge you to include that in title II.

With respect to title III we reemphasize our endorsement of the 3-year extension of legislative authority. We would urge you, however, to look perhaps a bit at the authorization levels in fiscal year 1980 and 1981. At least as we read them, they do not seem to make much of an account of inflation in these later years. We wholeheartedly endorse the proposal to give the Secretary of HEW authority to appoint the Director and the members of the National Cancer Advisory Council.

Lastly, we would like to enlist the good offices of this subcommittee in seeking modification of what we refer to as the "Sunshine" laws as they affect the operation of the peer review system. Several groups who have reviewed the peer review system and given it rather high marks—as I suspect you know—have all supported statutory exemptions to permit closure of peer review sessions when research applications and the qualifications of scientists are being discussed. In the final analysis, most discussion of basic research proposals revolves around the people doing it. Such closure protects the confidentiality of the peer evaluation and assures frank, uninhibited critique of research protocols and personnel. The patent and proprietary rights of investigators would receive greater protection and premature disclosure of clinical trials and similar data would be prevented.

Mr. Chairman, that concludes our testimony, we would be happy to answer questions.

Mr. ROGERS. Thank you so much, Dr. Carter?

Mr. CARTER. Thank you, Mr. Chairman.

How effective is the payback provision in influencing employment decisions of graduates?

Dr. GREENBAUM. Well, in terms of the predoctoral candidates that does not seem to be a problem. I spoke to many of our trainees and these predoctoral candidates seem to accept the payback provision as a necessary part of their accepting Federal funds.

However, my clinical colleagues advise me that at the postdoctoral level this is very destructive. That there are a group of physicians, M.D.'s, young M.D.'s, who wish to go into research, who have not been trained for research. However, if they learn of the payback provision they do not care to get involved in 1 or 2 years of training. Therefore, there are a great number of clinical postdoctoral positions vacant.

Another area of payback which is a bit of a problem is the fact that we do have medical scientist trainees whose program is 6 or 7 years in length before they complete their program. The payback here, it would seem to me, should be set at some maximum, such as 4 or 5 years, for these individuals, rather than have them fulfill 1 year for 1 year of stipend because they do have a great, long road to hoe. They are extremely important in our scheme of things in terms of putting out biomedical scientists.

Mr. CARTER. The tax bracket of the stipends, $3,600 to $10,000 taxes at a small percentage of annual income. Is this still a major problem?

Dr. GREENBAUM. Well, there is very great concern in the student community about this. As I mentioned in my testimony, the problem is that it is retroactive, as you noted yourself, to 1974.

Mr. CARTER. Yes.

Dr. GREENBAUM. The question is whether or not the stipend plus tuition will be included by the Internal Revenue Service. As I said, this means that some students might be liable, at a stipend level of $3,600 or $3,900, to a tax of $2,000, which seems inordinately wrong.

Mr. CARTER. I see. Should short-term training be given separate consideration in this legislation?

Dr. GREENBAUM. I do not think so. We have not discussed this point, but if you mean the summer courses or short-term courses, 8, 10, 15 week courses, it we could certainly live with amount of $1 million or so a year going to the short-term important programs, from the NRSA funds.

Mr. CARTER. Should basic research be funded with a percentage formula of total research funding, Dr. Curtis, or at the discretion of the Institutes?

Dr. CURTIS. We would urge that it be at the discretion of the Institutes, and an interaction between the scientific societies and the people interested in research, and the Congress. Percentages we would worry that our typical research areas would get gummed up.

Mr. CARTER. Yes, sir.

Dr. CURTIS. You keep chipping away at the wall, but nothing seems to be happening. Those are areas, we would submit, with a wide interaction we can pull a little funds back and put money, then, into areas that are more promising.

Formulas and percentages have a way of getting cast into stone long after the interests are gone by. We would urge that it not become a formula.

Mr. CARTER. Do you think the funding is adequate?

Dr. CURTIS. Adequate is a difficult word. Most of my colleagues find that there are a significant number of good research grants which are either not funded, or are not funded at reasonable levels. So that it is possible to use more money effectively.

Mr. CARTER. Yes, sir. This is in a different area. As you stated, there is a $20 million increase, I believe, in basic research for each succeeding year. In programs of the National Cancer Institute I see that there is only $3 million increase each year.

Dr. CURTIS. At first we wondered if that was a misprint, but we are told that it is not.

Mr. CARTER. Well, let us not blame everything on the administration, then. Thank you.

Mr. **Rogers**. I think the committee, in the language you were speaking of, wished to encourage the centers to provide continuing education programs for doctors and health professionals, as well to communicate the latest information of prevention programs in heart and cancer. Of course, one of the theories was that the centers would be spread over the country and would have a mechanism to transfer technology and the latest research knowledge quickly to the local communities in their areas. I think the permissive language is the Institute's language, not the center language.

Dr. **Curtis**. I see.

Mr. **Rogers**. We did make it very broad with respect to the Institute, but with respect to centers we have been specific.

I think we would want to continue that to make sure there is a communication between a center and the people it serves.

Dr. **Curtis**. We would applaud your design. On the other hand, I think it easy to think of a center which we would all wish to support as a center, all of whose members were "back room" boys. Then you end up either bringing in a second group, as it were, public interface—perhaps that is what you have in mind.

But I think we are worried that a group which is primarily constructed for research, some of which can be very "back room" boys, you may well upset and reduce the function of the center in what many people look upon as their primary mission. I would certainly support strong report language to in essence put NIH on guard that any center which they allow off of the public information, they are going to have to defend. But I think that we could easily find ourselves in a situation that none of us really wanted, in which the NIH ultimately had to deny funding to a center which was superb in any other way, but simply could not give itself up to this one regard.

Mr. **Rogers**. But of course, you also have an institutional grant, core grant, to provide support for some of the basics.

We were very anxious to have a continuing dialog between the center and the doctors of the local hospital, for instance, where they will be applying the latest research to people. I am afraid if we backtrack on that, we neglect to get that knowledge out as rapidly as we could. There are other possibilities, we will look at it.

Mr. Walgren?

Mr. **Walgren**. No questions, thank you.

Mr. **Rogers**. Mr. Maguire?

Mr. **Maguire**. Thank you, Mr. Chairman.

I am concerned, gentlemen, about the testimony relating to the Sunshine law. You would be surprised at how many different people can come up with plausible rationale for dispensing with one or another aspect of the Sunshine law.

I wondered if you felt there was any intermediate position between either having it or not having it apply in cases that you cited. Would there, for example, be any way in which the results of deliberations might in fact be made public, while the individuals concerned were protected, their identities were protected?

This is a very crude question. I am simply trying to assess whether or not there might be some intermediate positions which you might feel would serve the same purpose without closing off these deliberations, which are very important ones, from public scrutiny.

Dr. **Curtis.** Currently the results of the study sections are available. Within each study section two of its members are asked to review each grant. Their written responses are available to the applicant on request, without signature, much as we do when we referee articles for professional journals. We sign the one which goes to the editor, we do not sign the one which goes back to the individual.

Also, the study section secretaries will make available to you commentary on what was said, pointers as to the places where they found it weak. Those are internal NIH changes, some of which are fairly recent.

Yes, I think that is an intermediate step. I think that the specific comments now are available to applicants, and a general commentary by the study section secretary also.

Is that the sort of thing you had in mind?

Mr. **Maguire.** Well, I honestly do not know what I am looking for, I simply wanted to flag the issue as one which we might give some more consideration to. I frankly do not know what the answer is.

Let me ask another question. On page 3 at the top you indicate that you would favor short-term intensive research training programs which did not involve payback—short-term being defined as less than 1 year.

The philosophy of the payback, I guess, is that while we have a need—Mr. Chairman, you have been in this longer than I have and perhaps I am wrong in this—but where you have a need for some specific kinds of people, that it makes sense for the Government to provide some assistance; but with the understanding that it will be paid back in some form because we cannot, clearly, get into a wholesale distribution of Government funds to fund every kind of research project that everybody in every field might want to present to this Congress.

So, I wonder if in making that proposal you have given any consideration to the question of whether or not you favor the same kind of program to be available to people in other fields. For example, what would be your defense of the point that this would be giving unusual and very special privileges and monetary support to persons in a very specific, narrow field?

Dr. **Greenbaum.** I will be happy to talk to that point. I think we are not looking for just those students who are in the National Research Service Awards programs to get involved with these short-term intense courses. These courses would be open to all medical students, or all graduate students, or all students who have interest. These programs are tutorials on disseminating information on the latest methodology going on in molecular biology, or in pathology, or in various other areas of physiology. It brings groups of students to a center, and groups of faculty to a center.

Mr. **Maguire.** Well, would you favor that for students of religion, or students of history?

Dr. **Greenbaum.** Well, I think this works very well. I mean, this is an exciting and important aspect of education for our science-oriented students, and they have an opportunity early in life to see models and to hear from great experts as to various areas. This is part of scientific communication.

Mr. MAGUIRE. I know you like the program as it applies to people in the areas you are talking about.

Mr. ROGERS. Would the gentleman yield?

Mr. MAGUIRE. I would surely yield.

Mr. ROGERS. I think we are talking about programs here that are often no more than 2 or 3 weeks, probably a maximum of 3 months; and even the mechanism of payback is almost prohibitive from the cost of paperwork and so forth, for a couple of weeks' time.

Mr. MAGUIRE. If the gentleman would yield back.

Mr. ROGERS. Certainly.

Mr. MAGUIRE. The Chairman, I think, is suggesting something that is considerably more restrictive than what is suggested in the testimony.

Mr. ROGERS. Up to 1 year, if they drop out.

Mr. MAGUIRE. You can put an awful lot of 11-month periods of time together and can get an awful lot of support for an awful lot of things, it seems to me.

Mr. ROGERS. Well, I think we can look at that and make sure it is not abused, or the definition would not allow abuse.

Dr. GREENBAUM. We would not care to have that abuse, that would not be the purpose.

Mr. ROGERS. I think we could look, perhaps, at a restrictive definition.

Mr. MAGUIRE. Well, Mr. Chairman, I am going to want to look at whether or not we ought to be doing it at all, on a nonpayback basis; but we can discuss that among ourselves.

Mr. ROGERS. I presume there are some areas where we have done that with no thought of payback. In fact, we used to give scholarships and training grants without any payback. We have tried to initiate some program of payback, the gentleman is correct.

Mr. MAGUIRE. Thank you.

Mr. ROGERS. Thank you so much, we are grateful to you for being here.

We have as our next witnesses a panel of distinguished doctors and scientists, Dr. Mahlon Hoagland, who is president and scientific director of the Worchester Foundation for Experimental Biology; Dr. Lewis Thomas, who is president of the Memorial-Sloan Kettering Cancer Center; and Dr. James D. Watson, director of the Cold Springs Harbor Laboratory and a Nobel laureate.

We welcome all of these gentlemen to the committee. We are pleased to have you with us. I might say also, the committee is pleased to recognize the presence of a distinguished audience here who will hear you gentlemen testify, they are residents of preventive medicine from a cooperative program that is run by Emory and CDC. We might ask all of you concerned with preventive medicine, which is the way of the future, we hope, would you stand for us?

Mr. ROGERS. We welcome you to the committee.

We are grateful for the witnesses being here, and your statements will be made part of the record in full, without objection; and you may proceed as you desire.

STATEMENTS OF MAHLON HOAGLAND, M.D., PRESIDENT AND SCIENTIFIC DIRECTOR, WORCHESTER FOUNDATION FOR EXPERIMENTAL BIOLOGY; LEWIS THOMAS, M.D., PRESIDENT, MEMORIAL SLOAN KETTERING CANCER CENTER; AND JAMES D. WATSON, PH. D., DIRECTOR, COLD SPRINGS HARBOR LABORATORY

Dr. HOAGLAND. Mr. Rogers, members of the committee, we are delighted to be here again—we were here last month and had the opportunity of talking with you at length about our concerns about basic research.

We are speaking here this morning as individuals, but also as representatives of the small group that met with you last month, the delegation for basic biomedical research, which has been constituted this year to draw to your attention our concerns about basic biomedical research.

As you are all aware, the costs of health care in this country will soon exceed the $200 billion figure, and it is abundantly clear to us as members of the biomedical research community, and as members of the health care community, that a great deal more knowledge of disease is essential before we are going to make any significant strides in attacking them effectively.

I think that most of the public is unaware of the absolutely astonishing progress that has been made in the last 30 years in fields such as molecular biology, in developing an understanding of exactly what is going on in cells at the molecular level; and this, after all, is fundamental to our understanding of not only a disease like cancer, which you can take out of the body and study right there in a glass dish, but also many of the other diseases, such as cardiovascular disease, which we are now confronted with.

We have made astonishing advances in the field of vitamins and nutrition. We have extended human life expectancy by some 30 years. Our progress in diagnosis and treatment through the use of X-rays is a direct outcome of basic research. The freedom of women to choose their own patterns of childbearing through chemical contraception; the ability to do organ transplantation, to treat and prevent the major infectious diseases, some immunological diseases and so on, has grown out of, primarily, the search for knowledge by individual scientists working in their laboratories.

The cost savings are estimated now to be in the many billions of dollars annually on the basis of those diseases that have been eliminated and no longer require the attention of the physician.

Now, this Nation is spending, by my careful estimate, one-half of 1 percent of its total health care costs on basic biomedical research. We consider this an inadequate budget for basic research, and its inadequacy can be attested by the steady decline in the funding of research grants over the last decade.

Basic research has been subjected to a number of criticisms which relate to the question of "relevance" to social problems, and the question of whether its results are getting to the public fast enough. But I submit to you, sir, that basic research is relevant to the needs of society by definition.

Mr. Rogers. May I interrupt? This is the second call for Members to respond to a vote on the floor. If you will bear with us, we will vote and return immediately. So, the committee will stand in recess for 10 minutes. Sorry.

[Brief recess.]

Mr. Rogers. The subcommittee will come to order, please. Dr. Hoagland, I think we had interrupted you in the middle of your testimony. So, we will pick up from that point, and you may proceed as you desire.

Dr. Hoagland. Thank you, Mr. Rogers. I will finish the few remarks I wanted to make.

Mr. Rogers. Certainly.

Dr. Hoagland. I was making the point that nothing could be more relevant to the needs of our society than basic research because it works. History proves it works, to produce knowledge which gives us power to control disease and to control our environment.

There is no question in our minds that training of scientists and grant support for an effective working basic science effort go hand in hand, and your bill, Mr. Rogers, goes a long way toward meeting the training need. We have made the case in our testimony last month that basic science must get substantial support within each of the institutes, and we have suggested specific percentage figures. But I think the important point to us is that it be given adequate attention on a long-term basis by the Congress with whatever help we can provide as experts in that area, so that there is a balance between training and basic research in the various Institutes. In this way we can further the objectives of basic research optimally.

Mr. Rogers. Certainly, thank you. Who would like to go next?

STATEMENT OF LEWIS THOMAS, M.D.

Dr. Thomas. I do not have prepared remarks, although I would like to submit a statement later on, Congressman Rogers. I would think it best for my function here to be available to answer questions.

Mr. Rogers. Fine. Dr. Watson?

STATEMENT OF JAMES D. WATSON, PH. D.

Dr. Watson. Yes, I would like to discuss several things, particularly to Representative Maguire's question to research.

Mr. Rogers. It might be easier if you would pull the mike closer, and it would be easier for you to speak.

Dr. Watson. I would like to make a couple of points.

Mr. Rogers. Whatever you desire.

Dr. Watson. First of all, the payback procedures, there are complications. I can give you one small one. We have an American who had one of these awards with us. He then accepted a position in Canada, but then he was not eligible to do that. So, he would have to pay back because he was in another country. I think that is the sort of restriction on freedom which was likely unfortunate because it might be very good if such an individual would work, say, in England, France, or another part of the world.

So, it is a device which should be made fairly broad as to how you pay it back.

Second, with regard to the taxation, I think everyone is aware that it is almost impossible to live on $10,000 a year, and it is our experience with our postdoctoral fellows who do get awards of that size—if they have a wife and they have children—that they are living on their parents' income, or their past. Even $1,000 or $2,000 is a fairly large sum, and what we are giving them is just enough to live on, and, depending on the environment, not quite enough. So, institutions like my own have to help. So, I realize money is short, but this is just the sort of straw that is hard for an individual to take, particularly if it comes in several years.

The third point I would like to make is the need for courses like my own institution gives in Cold Springs Harbor, and why the payback procedure really will not work. We give courses in which we train advanced graduate students or postdoctoral fellows. They come for 3, maybe 6 weeks. Room and board plus tuition comes to about $700. They come to us because we will teach them something which is not yet taught in their institution.

We now have been told by the various parts of NIH that they cannot support us. Now, we cannot support such efforts because the actual cost of such a course turns out to be about—the tuition and total thing is perhaps $450, but it costs us about $2,200 per student to do it. So, we need a subsidy. I am so closely involved with them, I cannot say what we do is the best in the world, but I think it is awfully good and provides the sort of opportunity for new ideas to get a wide distribution fast. If you have a new methodology someone can come for 3 weeks and do it. You just need to be subsidized.

As to the general question why you should not do it for lawyers and theologians or something, I think that is the general question, why are we talking about the need to subsidize biomedical training. I think it is part of the same thing. If you want to extend that, you should argue for other occupations. I think that is too broad to get into, but I think our own program has been of major influence on science in this country and likewise the programs in Woods Hole and other institutions.

So, it is a small amount of money, and the various Institutes have said, we just need the authorization, we do not want to come in for a budgetary thing, it is too small for Congress actually to get into that—it is just the authorization involved; at least that is what they told me at the Institute of Mental Health.

The last point I would like to say is just to support the general thought that our greatest assets for the future are the people we are going to train, and that biology is still in an extraordinarily phase. The impact on medicine will be very great. So, I found my own enthusiasm for science as great as it was 30 years ago, there are so many things one can do, such as the whole basis of immunology, we will understand it. The new sorts of hormones in the brain, the neurotransmitters, it is impossible to believe they will not have very strong clinical applications. All this has come out of pure science and we should not feel ashamed, I think, for our accomplishments.

As to the question as to the number of people we should train, I think it is clear we have to. I thing it is clear, also, that the financial awards for going into this occupation are—with a few exceptions of people like myself who have sort of become celebrities—is dismal.

A full professor from Princeton was visiting me. He was thinking of leaving because his salary is $25,000 a year. Now, he is very well known. But that shows you where you are going to end up. So, it is not very high.

So, if we are going to sort of provide this to get people into it, make them choose an education which is not financially more remunerative, I think we are going to have programs which say, "We want more science," that is a fact.

As to the numbers, the great crisis now is the difficulty of people who are in their thirties, who are getting their first or second research grant. Morale is lousy, and the quality is high. Also, 15 years before we could have said the quality was low, and morale high. But, as a result of the success in the training in the past we have a large number of people, and I think the ability to realize that pure research is still our best weapon; that the Directors of the various Institutes of NIH should put the money where I think their heart lies, which is in the unknown, rather than sort of stretching things to bring applied technology in when it only gives us marginal improvements. We can do many marginal things with immunology, but there is a vast sort of center that we have to find out, say, before we can really pull off tumor immunology. I mean, our problem now is not of making tumor immunology work, but understanding immunology.

These sorts of problems—I hesitate to say it will happen too soon—but we have the people to do it, and we should keep this system going.

People in their thirties do not worry too much about their next grant. I think those are my general remarks, and I will gladly reply to questions.

Mr. ROGERS. Thank you very much, Dr. Watson. Dr. Carter?

Mr. CARTER. Thank you, Mr. Chairman.

I certainly want to compliment you distinguished gentlemen on your presentation, it is very fine, and of course you have my support all the way for increased funding.

I am very much a believer in basic research, and I support it. As it happens, I am supposedly on the conservative side of the aisle, but so far as you gentlemen are concerned, and health is concerned, I want to do whatever is necessary to be helpful, and I will. Thank you.

Mr. ROGERS. Mr. Maguire?

Mr. MAGUIRE. Thank you, Mr. Chairman.

Dr. Watson, I have just reviewed the basic law with respect to payback requirements, and I do not find anything in it that would have excluded the individual that you referred to on the basis of his having taken a position in another country. Perhaps there are regulations that do that, in which case, Mr. Chairman, I think we ought to look into that matter as a matter of policy because the regulations clearly in this case go beyond what Congress has provided in the law.

Dr. WATSON. They may be.

Mr. MAGUIRE. So, I appreciate the fact that you raised the issue, and perhaps we can look into it. I agree, it does seem senseless to have that kind of a requirement. Unless, of course, we are addressing this strictly to the manpower problems in the United States. If that is a concern, that may be the basis for the regulation. But we will look into that.

Dr. WATSON. Another point, in listening to the others, I might raise. Payback becomes available only after the first year, you are sort of excused in the first years. You do have a problem in that often people, you know, are not very good, and you do not want to continue them in their training so as to let them pay it back.

Can I express the point? Maybe I misunderstood the point, but if you have a certain number of years to be in the program before you have to pay it back, maybe after 2 years someone ought to just leave the accupation and be forgiven, rather than inflicted into an occupation where you should not be. So, we have to be careful about that.

Mr. MAGUIRE. There are clearly two categories of persons here. One is that for whatever reason are not qualified to complete the program.

Dr. WATSON. Yes.

Mr. MAGUIRE. Or do not wish to complete the program.

Dr. WATSON. Yes.

Mr. MAGUIRE. And others who would be entering for short periods of time for refresher courses, or some speciality, or what have you.

The statement that was made here by Dr. Greenbaum specifically referred to both of those categories of people. It may be that they ought to be treated differently.

Gentlemen, we have had a lot of discussion in recent months and years about the National Cancer Institute, and whether or not it is meeting the needs with its $800-plus million per year that it has had of public money. There has been increasing concern about the environmental exposures that apparently cause cancer in many cases. There is, I think, a commitment at the National Cancer Institute to expand and intensify their work on the preventive side, and they so testified yesterday.

I wondered if any of you might wish to comment on that particular aspect in general, and then I will make some additional inquiries of you with respect to particular proposals that I have made.

Dr. THOMAS. I might say something, sir. I am in agreement with the point of view alluded to in the remark you just made about the importance of increasing our understanding of environmental carcinogens, and to the extent it is possible identifying these; and to the extent it then is possible eliminating them from the environment.

I am in agreement that this effort has not been taken as far in recent years as it should have been, might have been. Perhaps to some extent that was because the scientific opportunities themselves had not sufficiently ripened, but I think the time is now at hand when this effort, involving public health, environmental medicine, epidemiology, and related fields can now be capitalized on with considerable scientific profit.

However, I would like to say that I think in addition we need a great deal more information than is now available, or can now even be guessed at, concerning the mechanisms by which carcinogens do whatever it is that they do because I am fearful that it might turn out in the final analysis that in a certain sense the earth is carcinogenic and there is no way out. If you get off a certain distance, then it is even more carcinogenic out there because of radiation. We are simply going to have to learn more than we know in hope of finding switches that can be turned, or mechanisms that can then be capitalized on for reversing or interfering with the action of carcinogens. We need both kinds of research, we need them badly, and I think the time is now ripe for both because of what has been happening, particularly in the field of intimate, intricate cell biology in the last several years.

Mr. MAGUIRE. Any other comments from members of the panel?

Dr. WATSON. Yes; I would like to make one. I have your bill you have introduced, and I would like to comment on it. It is very difficult now to collect the data that we want on such programs where they are given compounds that raise the incidence of breast cancer. Without a national register there is no decent collection of data; and any data, any feelings we have on the various forms of birth control pills will have to come from data in England where there is a death register, and the fact that they have been on the pill is recorded and checked through numbers. That is why we are awaiting the English data.

I think under your proposed amendment it would be very important to seriously consider what you can do with putting on some form of giant national computer relevant data, such as I know Representative Rogers is interested in, whether you worked in a naval shipyard.

That data could have been put down, and until we have such a scheme it is going to be very hard to argue increases of 5 percent, 10 percent, and we will be in a mess. So, it is nothing to be taken lightly because everyone feels that is going to take away our freedom; but I think it will give us freedom from unnecessary fear, which is, I think, equally important if one could be re-assured, "Yes, I have this occupation, but the data rules it out." As long as it is hearsay—and we have to remember that there are dishonest environmentalists as well as honest ones—the public is getting very confused. We will need hard facts.

Mr. MAGUIRE. Doctor, some critics of the idea have suggested that a national registry would require substantial funds and substantial efforts, and that mortality data by geographical areas would give us at least an approximation of the information that would be important to have.

Would you agree or disagree with that?

Dr. WATSON. Disagree. I do not think it is sufficient to merely pinpoint the things. I was at a meeting sponsored by the Biologicial Risk Assessment in Colorado Springs 2 weeks ago, sponsored by FDA, and there, when I asked the pill question, they said the American data will not do it. We are going to get the saccharine data, and that is going to be hard to get and it is going to be done in the wrong way. I mean, it is the only way we can do it, we are going to go back and try and get the proper controls. If the effect is large it will show it. But if the effect is small, it is going to be always hard to say whether you have the right group you are controlling with.

Mr. MAGUIRE. Your registry, would it be a tumor registry, or would it be a death registry.

Dr. WATSON. Death registry.

Mr. MAGUIRE. So you would try to set up a system to deal with all causes.

Dr. WATSON. Yes; so that you can do it. I think the cost will go down as the computers get larger and cheaper, and you have to be very careful not to put in unnecessary information. But, I mean, for those people who would say that DNA is dangerous, when our experience up to now is, there is no evidence of this. So, if the effect is marginal you will only do it by being able to take something and stick it in, and follow the figures. Otherwise it is your word against mine, and that is a very unsatisfactory way.

Up until now, until computers came along it would have been impossible for a country of our size. But I think with this we will not put American epidemiology, or not give it the great tool it needs unless we get it.

Now, you can get hints by going to a factory where a compound is manufactured and seeing the disease incidence, exposure is higher, and so you could say there are better cases to find it out. But in some cases you are not going to get data that way, and I think it would be a very important consequence of your bill if you would have set into motion a discussion—I am not saying do it, but I think it should be very seriously discussed.

Mr. MAGUIRE. My bill, of course, does not set up that registry, it simply suggests that that is a serious matter which ought to be studied and sensible conclusions arrived at; that is all my bill would do at this point. I assume everybody woud endorse that idea.

Let the record show that everyone is nodding affirmatively.

Dr. WATSON. But I think what I am saying is, you propose something bigger than you think you have because it is a major way, I think, to get health data. I would love to know whether eggs are good or bad for me, and I do not know anyone who is going to tell me.

Mr. ROGERS. What about jogging?

Dr. WATSON. Oh, that I know is bad.

Dr. THOMAS. I was going to say that it is "not bad."

Dr. WATSON. The second thing I would like to bring up, we frequently see that about 90 percent of cancer could be preventable if we had exactly the right environment. That, I think, misleads the people on how easy this will be to accomplish. If we did not eat, smoke, drink, or breathe, then it might be down to 10 percent.

Mr. MAGUIRE. Well, with all due deference, Dr. Watson, having made the rhetorical point I am sure you would go on to agree that there are ranges of things that we might indeed sensibly not expose ourselves to, and still eat, drink, breathe and live in this environment; and that we might cut into the problem in a very significant degree. Would you not agree with that?

Dr. WATSON. I agree, and I am trying to set up sort of an annex to our institute in Cold Springs Harbor which deals precisely with this point.

Mr. MAGUIRE. If it is not 90 percent but only 60 percent, or even 20 percent, if we could affect that many, it would be worthwhile; would it not?

Dr. **Thomas**. Cigarettes alone are accounting for 40 percent.

Mr. **Maguire**. And we well know that only a small number of the chemicals that we are exposed to have these carcinogenic properties, most of them do not. Is that not also true?

Dr. **Watson**. It is, but when we deal with important economic considerations, or important social issues, such if we banned hair dyes, it would be the graying of America—fast. That will be very hard to do. Very sensible people would say, "I do not really know the risk, and I know the risk of suddenly appearing gray."

Mr. **Maguire**. That is a risk you do not need to worry about a great deal.

Dr. **Watson**. No. But again, we are going to have to get the facts. I am saying that I think you could make an enormous contribution by helping us get the facts, which we have to do.

Likewise, if you ask, what really is the mortality of pesticide workers—no one is going to tell you, those people who are on those planes coming down. I was sprayed once.

Mr. **Maguire**. Well, I think it is clear we are concerned about people, as well as about scientific results, that we have to talk about registries, and we have to talk about screening of high-risk populations, which is another provision in my bill.

I would like to ask whether you feel—and I am addressing this to all the panelists—that some of the specific proposals I have made about making NCI the lead agency, but asking that they report annually on what we know about carcinogens with respect to the scientific data, what the regulatory situation is, what recommendations ought to be made, and whether we ought to have some people on the board who have expertise in environmental carcinogens, et cetera, whether those recommendations seem to you to be helpful ones. Let us start with Dr. Hoagland.

Dr. **Hoagland**. I would like to respond in a somewhat more general way. I would like to get back to what Lew Thomas has just said, and that is that I have some considerable concern that the National Cancer Institute over the last 7 years of its existence has shown a tendency to fractionate itself into different kinds of activities, many of which, many of us feel, are not directed at the fundamental problem of understanding this dreadful disease. I think as long as we are spending large sums of money on half-way measures, and on attempts to do partial approaches to cancer problems, we are going to continue to be in serious trouble and costs are going to continue to rise.

I do want to say this, in respect to the environment, and in particular in respect to your bill, Mr. Maguire that attention to the environment is very important. My concern is simply that we do not shortchange basic research, the study of the cancer process by introducing new programs. I do not think we need to.

Mr. **Maguire**. I agree with that. Now, my question, though, would be, what are the half-way measures that you are referring to, which you think have not been as useful to pursue, assuming that we like basic research and want to do something about prevention. What are the things you feel have characterized the misdirection. Could you be more specific on that?

Dr. **Hoagland**. I believe that in general a number of programs which are very expensive involve essentially patient care, drug testing, various aspects of chemotherapeutic programs, and in general activities supported by many contracts. These all need a great deal more careful scrutiny in terms of the quality of the scientific data that is being obtained. I think that we make a rough estimate that some $350 million out of the total budget of $850 million are being devoted to what we call basic research, project grants, program projects, and so on in the Cancer Institute. The remainder of that money, a very substantial fraction of that budget, 60 to 70 percent, is going for activities that we feel are less likely to be productive in terms of ultimately helping us to deal with cancer effectively—that is by reducing mortality and morbidity statistics. And so far very little improvement has been seen.

There are clear-cut instances of very dramatic and exciting developments in programs in the Cancer Institute affecting small numbers of patients but they are few, and they are not affecting the overall mortality and morbidity.

Mr. MAGUIRE. I found that a particularly helpful statement in view of the fact that I agree with you.

Mr. MAGUIRE. Dr. Thomas, do you have any comments?

Dr. THOMAS. I would like to qualify it a little bit. I would like to say first of all that I am in support of the measures in your bill, and particularly in support of having the NCI charged with the responsibility of taking the lead role in this, so that it does not get scattered throughout government as loosely as it now appears to be.

I do think that this should be done, however, not at costs to the basic science program of the NCI. I would hope that the costs of funding will be added on to the NCI budget.

Mr. MAGUIRE. I agree with that. But if Dr. Hoagland is right that 60 to 70 percent of the budget is not going to basic research, or the things that we are talking about here but for other things, then there is plenty of room for some redirection.

Dr. THOMAS. That is my qualification, I am not sure how much room there in fact is. I have some anxieties about the definitions you use for basic research these days, one that I know Dr. Fredrickson has used is just arbitrarily to say all the investigator-initiated grant research is to be designated as basic science. For operational purposes I suppose that can be a useful way of defining it, but I would want to be sure that when you count up the total amount that the NCI is putting in the basic science, that you would not leave out the program-project programs, which are very large; nor the center programs, which are large.

As far as clinical science is concerned, although Dr. Hoagland is correct in saying that the chemotherapeutic studies have not yet yielded large-scale—in terms of numbers of patients—positive results for the major forms of cancer, such as cancer of the lung, which remains a disappointment, it is nonetheless immensely exciting and very encouraging to the cancer community to observe that what used to be regarded as the most malignent, and the most rapidly lethal of all forms of cancers—cancer in childhood—are now responding to new chemotherapeutic agents given in combination, in ways that we simply could not have imagined happening 5 or 6 years ago. And there are now instances of what I think will turn out to be outright cures of very important kinds of cancer which seem to disappoint the public because they occur in only relatively small numbers of people.

But the leads that are emerging from those positive results will I am confident, have bearing on the directions that we will take henceforth in trying to cope with lung cancer, breast cancer, and the rest.

So, I am not discouraged about that. I do think that as much tightening up as possible of the standards for judgment before launching large-scale clinical trials and therapeutic studies are very, very important because of the overall shortage of money.

Mr. **Maguire**. Dr. Watson, did you want to comment? The chairman is being very generous.

Mr. **Rogers**. His generosity is about to give out.

Dr. **Watson**. I will comment on two things. One is, how do we reconcile two statements, the sort of general statement that things are good for cancer research, and yet, we are not curing as much cancer as we want.

Mr. **Maguire**. Or preventing.

Dr. **Watson**. Or preventing. I think there is something we will only begin to feel over the next decade, which is, I think, a great maturing of the cancer research community, with people who are now very good, in their thirties. This did not exist when the war on cancer started, and I think a lot of money was seized by third-rate people. With proper, real hard looks at who is getting the money, these things should stop and the money which is now authorized could be all well spent.

Mr. **Maguire**. That raises the question, of course, of the recent revelations of the Institute and other institutes, and perhaps you would weave in some comments on that.

Dr. **Watson**. Yes. Now your bill, I mean, it is not enough to have people who call themselves environmental carcinogenists on the board because we had one on the board. So, Phil Shubick was on the board. So, by saying that we have to have three or four people on the board, it is who is on the board that is important.

Mr. **Maguire**. Well, Dr. Selikoff said yesterday that if we required six, we might get two that are good.

Dr. **Watson**. Well, I think you will get better people now because the science is growing up.

Mr. **Maguire**. Well, it still depends on who is appointed, as a result of the kind of political process by which they are appointed.

Dr. **Watson**. Yes. I think the changes that Dr. Upton wants to put through, which Mahlon disagrees with, but which I think superficially look good, which is to have better cooperation of the contract program and the grant program; so that if someone is getting a contract he is aware that he has been consistently turned down for years by peer review, that will become more obvious. So, I think what Art is trying to do is a very good thing.

Now, some people worry that it will be misused because the contract people will seize control of the grants. Well, I think you have to be optimistic and just let them go and see what happens; that is my belief.

Now, to get back to environmental carcinogenises because the registry is going to be at the heart of the matter, I want to say this because you have money concerned, and you have arbitrary things, and we are going to have to get the data. I think we should concentrate now, in the next 10 years, on getting the data. Now, you say, what about all those people we might have saved? But we cannot ban everything. So, unless the risk is just overwhelming, such as Tris. I mean, Bruce Ames deserves any medal anyone in the world can give us because of that test and getting that out of our children's clothes. I have small children, that is why I feel so strongly about this.

Mr. MAGUIRE. If you have tumors caused as a result of exposure to chemicals that are included in hair dyes, do you not then, on the same argument, have to look at that with respect to action that you might have to take?

Dr. WATSON. Yes, I would. But I am saying that is a political one. On the one of our children, they have no choice, that was put in. On the question of hair dyes it is going to be cancer——

Dr. THOMAS. So is smoking.

Dr. WATSON. Yes. So, it is a difficult thing. All I can say now is, I would not let my wife or anyone I know get near them; this is my own personal thing. But I realize the political complexities of banning something, that is all, without the data.

So, what you should do is to give the National Cancer Institute, which is the correct body to do the work—it should not be FDA, it cannot be EPA, they do not have the technical expertise, it would be silly to duplicate it—it should be the Cancer Institute's responsibility. We have a new Director that knows that, he is good. But we cannot bite off too much right now. If we get the data then our citizens and you as Congress can act wisely.

Mr. MAGUIRE. Well, when you say "data," you are referring to epidemiological data.

Dr. WATSON. In some cases.

Mr. MAGUIRE. You do not mean to suggest that bioassay data is not sufficient to base policy decisions on, I hope.

Dr. WATSON. No, I am saying I would like to do it, but it is going to be very hard politically, in some cases, to do it.

Mr. MAGUIRE. But the political question is not the question. The question is whether or not bioassay data gives you data that is the best we can have at any given point in time, otherwise you are going to count bodies over the next 20 years and then come up with a policy.

I think this is a discussion we should have another time, Mr. Chairman.

Mr. ROGERS. It is a very fascinating discussion.

Let me ask this—and I will just ask a few questions—what about comprehensive centers? Should we include the requirement that basic research be supported by the core grant, or not?

Dr. THOMAS. I have a certain bias.

Mr. ROGERS. Well, you run one, so I think that it would be good to get your reaction.

Dr. THOMAS. I think it is of crucial importance that the core grants for the comprehensive centers be used as they were when they were set up with the support of the basic science effort. I think it is of crucial importance for institutions like the one that I am responsible for, that salary money, some salary money for the scientists involved in leadership roles within the institution be provided from the core grant.

There is a difference between the comprehensive cancer centers and the rest of the university and academic science community in this country since a good many of them do not have the same kind of tenure commitments available to them that exist elsewhere in, say, the medical schools or the universities. Therefore, it is more difficult to enlist the kind of first-class scientists that we need for such institutions if all of them have got to generate salary money out of their own grants. The same thing applies for the ancillary services that are necessary for research.

Mr. ROGERS. I think if you could give us any idea—for the record, I do not think you have to do it now—if you would give us some thought and let us know within the next week or 10 days, if you could, your thinking of whether there should be any shift in direction of the core grants, and to what degree.

Dr. THOMAS. I have been giving this thought day and night, especially at night.

I would be delighted to.

[The information requested was not available to the subcommittee at the time of printing.]

Mr. ROGERS. Thank you, that would be very helpful. To what extent should the centers stress prevention, as opposed just to treatment?

Dr. THOMAS. Well, if the centers do not stress prevention, no one else is likely to. The difficulty that the centers will have in this regard is that the underpinning of scientific information necessary for genuine and large-scale prevention programs has not yet been assembled. We do not know how to prevent very much of anything at the moment on anything like a substantial scale, other than cancer of the lung through the prevention of cigarette smoking.

Mr. ROGERS. Dr. Watson, I think you wanted to comment.

Dr. WATSON. I am not thrilled by the concept of the comprehensive center because I think it almost tries to do too much. I think it is very important that we have as many as possible first-rate hospitals for the treatment of cancer, such as Memorial Hospital. The more of these we have the better, so that when people go there they are treated correctly. We should do everything possible to increase that.

Putting within the same administrative fabric pure science runs into a lot of difficulties because there is a different allegiance, and there is a different sort of time scale. The physicians want to save their patients, and we are sort of thinking maybe of 20 or 30 years apart. I think the setting up of more specialized centers without such broad mandates might be more productive.

Mr. ROGERS. More of the minicenter concept, is what you are talking about?

Dr. WATSON. Minicenters with specific goals. For instance, I think the country could well afford three or four first-rate centers in chemical carcinogenises—we do not have those. That would bring together the sort of grouping that I think would get out the data. I think if you place them next to, or within first-class intellectual centers where they have the contact with the chemist, and so on, it will work. Memorial is across the street from the Rockefeller, and they have quite an intellectual center. In some cases you are really isolating people from the people they should be with.

So, I think—and here I speak just as prejudiced because we have a minicenter in Cold Spring Harbor, and I think by a sort of limited objective we can control the quality. I think if you ask one individual to do so much, you may lose your cost effectiveness unless you can say there is real interaction between the groups within it. It is one thing to say that cancer control should be carried out in Seattle, but it is not clear where you should put it. That, I think, should be resolved.

Mr. **Rogers.** Thank you.

Dr. **Hoagland.** Could I just comment briefly on that?

Mr. **Rogers.** Sure, Dr. Hoagland.

Dr. **Hoagland.** As the director of another minicenter, and as one with great respect for the Memorial Sloan-Kettering Comprehensive Center in particular, I think that this country faces very difficult problems with respect to cancer centers. There is a terrific pressure, I understand, for the creation of more and more comprehensive cancer centers; and in my experience some of those I visited have the problem of serious underfunding anyway, so they really cannot accomplish the mission which they have received as a mandate from NCI.

I think the pressure that we see, to increase the largely clinical comprehensive cancer centers, is that the small specialized basic science centers, devoted entirely to basic research in cancer, are being squeezed out. There is already talk of taking away from us those very salaries for our scientists that we need desperately in order to keep an effective operating unit.

I think somehow this Government supported proliferation of essentially "doctoring" operations has got to be very thoroughly examined as to how far are we going to go with centers. I do not think it has been grappled with yet on a broad policy basis.

Mr. **Rogers.** Would you want to comment, Dr. Thomas?

Dr. **Thomas.** Just to say that there is a middle ground, I think, in this kind of argument. I have no doubt at all about the value and the need for comprehensive cancer centers, I just do not know how many we need. But I would hate to see us uncouple the clinical science community from the basic science community within the institutions that do have a competence for studying cancer in human beings because the problems of human cancer are not entirely matched by the experimental paradigm that we have for cancer in animals. The time is about right, as I think we are finding in our own institution, for frontal and basic studies on cancer as it exists in human beings.

Mr. **Rogers.** What about the cancer control program, is it effective; or would you propose changes?

Dr. **Thomas.** I would propose only one change. I think the cost of that program is going to continue to increase, and since it is in such a great degree a program, essentially, of clinical care, I think it should be funded from some source other than the research funds allocated to the NCI. I would feel more comfortable about it if it were funded from some other part of HEW, rather than NCI, because of the anticipation that I have, that it will continue to grow.

Dr. **Hoagland.** I would like to support that strongly.

Dr. **Watson.** Yes. I will again come back to the data question. We will never be able to know whether any of these programs work without a national death register because the people move, whereas you have one in a city and you give it up, people think they are losing something. But, how do we know they are losing something unless we get statistics? So, we have to get the data.

Mr. **Rogers.** Sure. Now, how about the peer review mechanism, are you pleased with that; or should there be changes?

Dr. **Thomas.** I am pleased with it, and the changes that I would like to see happen would be simplifications, or reduction in the amount of paperwork, and an effort made to continue enlisting the participation of your very brightest young scientists in the country.

But I think as social inventions go, that one is one of the marvels of this century.

Mr. **Rogers.** Any other comments?

Dr. **Hoagland.** I agree with that statement completely, and the only thing I would like to add is, I think many of the study sections are heavily overburdened now with multiple applications coming in from individual scientists; the number of sections should be increased.

Dr. **Watson.** My only answer to Mahlon's question, because some of my staff are on study sections and I know how much time they devote to it, is that with funding being for such short-time intervals, with the number of applications which come in, that we are really building up momentum of futility. I mean, if you only give money for 2 years, and good people only get money, an increase of the length of time of funding will enable better reviews to be made, and I think that the system would work better.

As far as the Sunshine procedures, there the system will totally fall apart if we have to open those up. I think every person should receive the pink sheet, which has assessed his grant so he knows what it is, but to be in the room—it is bad enough now. Most of the people do not like to say nasty things about anyone else. But under these circumstances where they have to compare a with b, they have to say something. It is often pretty mild, but imagine if the people were in the room, nothing would be said; and then we go out to lunch and say, "Now we will make the decision."

Mr. **Rogers.** Should the proceedings be transcribed? Maybe not with the applicant present.

Dr. **Watson.** I do not think they should be because I think it would just be, again, more paperwork; it would not help anything. I think the secretaries of the various study sections do quite good jobs in summarizing.

Mr. **Rogers.** Every scientist has the right to have the reviews given to him.

Dr. **Watson.** Yes; so he can see what it is. I think having an official sort of appeal body is probably not worth it. The reason why I say this is, we have such a multiplicity of funding as it is now in the United States, that is almost appeal. If you had only one funding, you did not have NSF, you did not have the American Cancer Society—but if someone has been turned down by five bodies he is also going to be turned down by the appeal board.

Mr. **Rogers.** I think any suggestions you may have for the record for cutting down paperwork would be helpful to have.

I have heard that it is difficult, though, for young scientists with new ideas to get funding. Is there any legitimacy to that?

Dr. **Hoagland**. Mr. Rogers, let me respond to that by saying that I think it is very, very difficult to get really solid, hard figures on this question of how underfunded good scientists are. In general, I think, it is the consensus of the scientific community that many of our ablest young people simply cannot get funded. Also, many of our older scientists cannot.

We did a minisurvey in our institution recently, asking, how much time do our individual scientists spend of their total time available for research on writing grant applications, and the figure came out about 20 percent of the 40 scientists in our institution. I sometimes suspect it is more than that. But at any rate, scientists today are spending a great portion of their time on grantsmanship and on writing applications.

Mr. **Rogers**. Can anything be done to simplify that?

Dr. **Hoagland**. Well, I believe the best thing to be done, is to make more funds available so that a reasonable number of the better of our scientists are getting funded. The situation was that way in 1967 and up to 1967. Although our total budget is much higher now, we have many more able people who want to get into science, and I think they should be allowed to get into it.

I think if the pressure was off in terms of funding, we would not have that difficulty. We would not have the difficulties with the study sections.

Mr. **Rogers**. Thank you. Dr. Carter?

Mr. **Carter**. Thank you, Mr. Chairman.

I was very much impressed, Dr. Thomas, by what you said about turning disease off like turning off a light switch, I believe that was your implication.

Dr. **Thomas**. Yes.

Mr. **Carter**. And it has almost been done, for a time. In most cases only for a time. Is that not correct?

Dr. **Thomas**. Well, there are a number of diseases which used to be of major importance, used to be regarded as multifactorial chronic diseases affecting five or six different organ systems, and about which we used to think that they could not possibly be due to one cause, they must be due to multiple environmental influences, or lifestyle, as determined today, has it. One was pellagra, one was pernicious anemia; pernicious anemia being perhaps the best example of all, in which it was discovered when the facts were in, that a single vitamin deficiency switched off mechanisms that were destroying central nervous system tissue, spinal cord and brain, parts of the gastrointestinal tract, bone marrow, blood elements, and so forth.

Mr. **Carter**. You have given a good description.

Dr. **Thomas**. The only diseases that we do really understand today seem to be governed by a single principle central mechanism. To be sure, there are multiple influences, and I am sure this would be the case with cancer, it will be many environmental carcinogens and even possible many viruses at work.

But my own private hunch is that at the center of things there is a "chairman of the committee" somewhere in the cell, and we have not yet identified that governing mechanism. When we do, I think it will place in our hands the equivalent of the switch.

Mr. Carter. That, I have seen. We have seen cases of leukemia that absolutely just turned off for a number of years after treatment, say, of 50 or 60 days.

Dr. Thomas. Yes.

Mr. Carter. First, it would be impossible to identify them as having this disease. And suddenly recurrence takes place. The switch may work one more time, you may turn it off for a little while, but that is as far as it goes.

Dr. Thomas. It goes further than that in children.

Mr. Carter. With some of them, yes, sir; I have followed some.

Dr. Thomas. It is much more encouraging.

Mr. Carter. Yes, sir, that is true. Are you aware of Dr. Martell's research on the role of insoluble internal alpha-emitting particles inducing cell mutations and carcinogenic changes?

Dr. Thomas. No.

Mr. Carter. Are any of you?

Dr. Watson. The name was what? I did not catch it.

Mr. Carter. Martell.

Dr. Watson. No, I am not.

Mr. Carter. These particles come from various types of radiation which are emitted in the environment, and they are contained in most of our food and plants. It is an unusual theory that 95 percent, perhaps, of our cancers may be caused by this ingestion of these alpha particles. They stay within the body and by their action cause mutations which continue in the form of cancer.

What is your opinion of research contracts, doctor?

Dr. Thomas. I do not know what the percentage figure is, but research contracts are absolutely essential for the provision of viruses, enzymes, antibodies, special lines of mice that are required for research. There is no better mechanism than the contract mechanism.

For the doing of basic science, I think, the contract mechanism is inappropriate. I would be vastly encouraged if the contract now being used for doing basic science were somehow moved over into the investigator-initiated project grant. It is easier to review; it is easier to be sure about the quality; and I think it is a healthier way of doing science.

Mr. Carter. Yes, sir. Have these contracts led to an excess of funds being shifted to applied research?

Dr. Thomas. I cannot answer that because I do not know the facts and numbers in enough detail. I think there is that risk involved. I think before applied research is done in medicine because of the vast expense involved and because of the large number of personnel that have to be tied up in applied science ventures for long periods of time, I think the standard should be kept very high indeed.

Mr. Carter. Yes, sir. The considerable expense of funding centers and moving funds into more plant-type research is necessary, do you think?

Dr. Thomas. No; I do not think a large amount of money is needed for more applied science than is going on at the present time.

Mr. Carter. Would you favor a reconsideration of the magnitude of funds for the centers?

Dr. Thomas. Well, you know, the centers are receiving funds as centers only through the core grants.

Mr. **Carter**. Yes, sir.

Dr. **Thomas**. All of the other funding for centers is investigator-initiated or contract research done out of individual groups or individual scientists, just as it is going on in the rest of the scientific community. So, the magnitude of the investment the country is making in the comprehensive cancer centers is to be viewed as the sum of the core grant program. I do not regard that as an excessive investment at the present time.

Mr. **Rogers**. Would the gentleman yield?

Mr. **Carter**. Yes, sir.

Mr. **Rogers**. How much, would you say, basic research comes out of your core grant at the present time? Doesn't the investigator usually apply for a separate grant?

Dr. **Thomas**. Most of the basic science comes from the core grant if you look as seriously as I do at the salary money, or the portion of the salary money for the investigator that is in the core grant, plus the money that goes into the maintenance, for example, in our institution, of the highly specialized colony of inbred mice and other specialized ancillary facilities. So, I would say it is a very important element in the support of basic science, but it is not the only one, obviously because the investigators are generating their own grants, just as everyone else does.

Mr. **Rogers**. Thank you.

Dr. **Hoagland**. Mr. Rogers, could I just respond to that?

Mr. **Rogers**. Certainly.

Dr. **Hoagland**. In our institution, which is a small, specialized cancer center, we received about $400,000 a year as a center, a core grant; and about $1.8 million in grants obtained by those individuals whose salaries are paid by the core grant. So, the two are absolutely essential, but most of the money comes from individual grants.

Dr. **Watson**. The difficulty is with the research grants being for decreasing lengths of time, and when people's salaries are coming out of that, this becomes a nightmare to directors of institutions. What any director wants, if he does not want to think about his work at night, is at least knowing that his staff is going to be paid over the next couple of years. That is what I think core support can give.

Now, I think the problem—and I have been off the Cancer Board quite a while—but the way I saw it, all their projections on centers were based on a magical number of $1 billion for cancer research, that is what Lee Clark wanted and thought he was going to get. That was $1 billion without an inflationary factor. Things have stayed clearly constant. A number of centers were created—I think too many—and most of them without the resources, really, to do their mission very well. So, there is a lot of realization that they are hollow shells, but no can blame them because there was not the funding to make them more than that. So, you have major problems. That is why some of the criticism. You can get good ones, but you can get others where people have a very hard time because they are being asked to do more than they have resources for.

Mr. **Rogers**. Thank you. Dr. Carter.

Mr. **Carter**. Yes, sir, Mr. Chairman.

How do you recommend giving more attention to basic research activities?

Dr. **Thomas**. One mechanism, and I must confess the easiest one that, I must confess, pops into anyone's mind, is by increasing the commitment on the part of the total NIH in financial terms to basic research.

Another possibility which we have discussed, and we were talking about when we were here last month, is to increase selectively the budget of the Institute for General Medical Sciences in order to be sure that the kinds of basic sciences that do not fit neatly and tidily into any of the categories of disease efforts, will not be missed and will continue to be funded. We have that advocated, a large-scale and significant increase in the research project part of the budget of the NIGMS.

Mr. **Carter**. Yes, sir. What about FDA, does it release new drugs to you; for example, drugs you want to use in cancer treatment quite readily for your institution?

Dr. **Thomas**. We have not had difficulty at Memorial Sloan-Kettering in procuring or getting approval of new drugs, as yet. We live in some apprehension about the future, but so far we have had no problems.

Mr. **Carter**. Well, I have seen some institutions complain of these drugs not being released.

Dr. **Thomas**. That is not to say we do not complain.

Mr. **Carter**. You do complain?

Dr. **Thomas**. We complain, but we have been successful in getting on with the studies.

Mr. **Carter**. In cases where the course is known, where the patient is going to die, perhaps shortly, I think, the drugs would be released on your request, or on the request of two or three investigators. At the least, they should be released, if you know the patient is going to die immediately, or within a short while without something that is being done. We do know in some cases where patients are expected to die within a very few days and they are saved by chemotherapy, at least for a time. In those cases, if you ask for a drug, I do not know but that it should be given to you.

I am very much interested in the register which you propose. We have an agency for statistics which, really, it would seem to me would be the proper area for this to be done.

I do think that it should be complete and comprehensive where you can associate diseases with the environment, the different elements of the environment, as it happens to be; and by that association you might be able to tell why certain tumors come in certain areas. I think that would be extremely helpful.

The distinguished gentleman from New Jersey who was here this morning, of course he has a serious problem—go right ahead.

Dr. **Watson**. It can be extremely expensive to go on single instances and get the data. I was told of a case of the Cancer Institute worrying about men who worked in the upper regions of steel mills——

Mr. **Carter**. There is no such thing as a free lunch.

Dr. **Watson**. So, it was about $4 million, or something, to collect this data, which was an extremely small occupational group; and they did find that if you were working in it, your frequency of lung cancer went up, which does not surprise me.

Mr. CARTER. Yes, sir.

Dr. WATSON. If you are going to cover all the groups who may be affected, you have to do it in a more systematic way.

Mr. CARTER. Well, I think we have in place an agency that can do it if we expand its work, yes, sir.

Thank you, Mr. Chairman.

Mr. ROGERS. The committee again expresses its appreciation to you, and if you could let us have for the record your thinking; and we may have a couple of questions we would like you to give us your opinion on, that would be helpful.

Dr. HOAGLAND. Yes, sir.

Mr. ROGERS. Thank you for your presence.

Dr. THOMAS. Thank you very much.

Mr. ROGERS. The committee stands in recess until 2 o'clock this afternoon.

[Whereupon, at 12:40 p.m. the subcommittee recessed, to reconvene at 2 p.m. on the same day.]

AFTER RECESS

[The subcommittee reconvened at 2 p.m., Hon. Paul G. Rogers, chairman, presiding.]

Mr. ROGERS. The subcommittee will come to order, please.

We are continuing our hearings regarding the "biomedical research and research training amendments of 1978, and this afternoon we begin our hearings with Mr. Jacob Clayman, who is president, secretary-treasurer, Industrial Union Department, AFL-CIO, accompanied by Sheldon W. Samuels, director of health safety and environment.

We welcome you gentlemen to the committee. We are pleased to have you.

Your statement will be made a part of the record in full, without objection, and you may proceed as you desire.

STATEMENT OF JACOB CLAYMAN, PRESIDENT, SECRETARY-TREASURER, INDUSTRIAL UNION DEPARTMENT, AFL-CIO, ACCOMPANIED BY SHELDON W. SAMUELS, DIRECTOR, HEALTH SAFETY AND ENVIRONMENT

Mr. CLAYMAN. Thank you, sir.

Mr. Chairman, and members of the committee, what I am about to say may appear to be flattering to several of you on this committee, but indeed it is meant earnestly.

Mr. ROGERS. May I say this committee can always stand some flattery. Isn't that right, Mr. Maguire?

Mr. MAGUIRE. We get precious little of that, Mr. Chairman.

Mr. CLAYMAN. I feel good about that. You even encourage me to gild the lilly.

If we have not appeared before you in prior hearings, at least part of the reason is the sense of security derived from your long and wise stewardship and the care and interest of members such as Congressman Maguire. Until very recently, the first weapon in the war against occupational cancer—OSHA—was in weak hands, unfortunately. I think you can understand why that has been the focus of our attention. That situation, under the leadership of Dr. Bingham, has changed. And I might say, parenthetically, dramatically, too, for the better.

The second weapon, a national cancer program that includes serious attention to the problem is only now being forged in NCI—after years of neglect. That progress must be credited to the initiatives of the new NCI Director, Dr. Arthur Upton. Our purpose today is to reinforce his initiatives, to make sure that his efforts become a permanent part of the Nation's war on cancer.

With the unfolding implementation of the Occupational Safety and Health Act for the first time we are beginning to see the total situation. It is much worse than we anticipated. While we can adjust our objectives to our new perceptions, there remains a glaring void caused by our failure in the past to develop an effective program of biomedical research and intervention for high risk worker populations. That is not a failure which can be perpetuated.

It is not possible to provide a meaningful estimate of the total number in all high risk populations because of the lack of data, the continuous addition of new agents and processes to the "known list," and the necessary assumption that large numbers of workers are in more than one population because of multiple exposures.

Nevertheless it is fair to say that millions of people are at high risk and can be expected to die of cancer and other irreversible diseases at increasing rates proportionate to the rate of the industrial development of the past 45 years if we do not develop a national program of intervention.

But it is also fair to say that not everyone in a high risk population will develop an environmentally related irreversible disease. Rates depend upon factors of individual biology and individual environment, such as heredity, duration of exposure, differences in the biological activities of the agents themselves, or their metabolites, and the mode of exposure.

What we have found is that there are millions of workers, farmers and small businessmen whose past exposures have placed them at high risk of developing occupational disease. We are talking about 7 to 8 million workers currently exposed to regulated and unregulated carcinogens, and just the recitation of those figures must strike terror into all of our hearts. We have no idea about how many are at risk for other irreversible diseases. The National Institute for Occupational Safety and Health estimates that one in four Americans may have had exposure to OSHA-regulated toxic substances.

For these workers a perfect OSHA program, supplemented by the toxic substance control program in EPA, may do nothing—for these millions prevention may indeed be too late, yet they may not have clinical disease. Thousands more do have clinical disease, but could not be aided by a perfect health care delivery system no matter what.

One of the most important concepts repeatedly established is the long period of clinical latency between onset of exposure or, perhaps more accurately, "effective" exposure, and evidence of clinical disease. This "silent period," so called, between initial effective exposure and the discovery of disease is of more than theoretical interest. It offers an opportunity, a possibility—because of the delayed appearance implied—that intervention during this time might be successful in breaking the chain of events between exposure to an agent and uncontrollable disease. While there are no guarantees, we should at least try to break some of the links in that chain. We must learn how to address the problem early enough.

Add to these problems the rediscovery of largely unquantified and neglected bystander and family effects of occupational exposure, and, indeed, you develop a problem that is big enough for all of us to aim at. Just parenthetically, I remember when I first learned that wives and members of the family would contract diseases from asbestos and other contaminants brought home on the clothing of the worker that had never been conceived before. Suddenly one became aware that it wasn't just the ordinary worker in the factory environment who was subject to debilitating diseases, but it could be conveyed readily to the family at home and even to the progeny thereafter. So I think we get a small sense of the breadth of the problem we are struggling with.

Mr. Chairman, with very few exceptions, we have not learned how to deal with this crisis: how to identify and intervene in the development of environmental disease among exposed populations. Nor are we making enough of an effort to learn.

Significant—albeit insufficient—progress has been made in the identification of a large number of environmental agents associated with irreversible occupational disease. Predictions ridiculed by industry and ignored for many years by those in government and academia whose judgments were swayed are being realized. Unless we achieve an amendment to the laws of nature, without preventive, preclinical and clinical intervention the biological implications of uncontrolled industrial activity in the past mean future widespread disaster—disaster, not only in terms of needless suffering and death, but also in terms of uncontained social costs that fuel inflation, unemployment and other symptoms of our faltering ecenomy.

Those laws of nature do not prescribe inevitable failure. The record of the past is not the experience upon which we can predict the future. Indeed, we have reason to believe that a generation of basic research is beginning to pay off.

It was on the basis of such research that the National Institute for Environmental Health Sciences was able to move quickly in the kepone disaster and enable the development of the clinical means to remove the pesticide from the bodies of kepone workers through treatment with the drug cholestyramine. Surely, the risk of cancer remains, but just as surely that risk is greatly reduced.

We realize that the failures of the past include some NCI efforts, such as the programs in Tyler, Tex., for asbestos workers and in Louisville, Ky., for PVC workers. But studies that are poorly designed, loosely administered, lacking in technical support do not constitute an adequate test of the abilities of our national cancer program. We don't begin to have long-term surveillance studies of severely exposed workers adequate in numbers and quality—if the committee would care to have a description of why the two programs I have just described didn't do well, Sheldon Samuels, who is with me, I think, can elucidate on that.

The Federal Government must see to it that research efforts among those unfortunate workers who suffer massive exposures are coordinated, that studies are designed from the start to yield useful results, and that extended funding is available to maintain the undramatic, but vital, registry and followup programs. This requires a larger number of studies, provisions for extended followup—and we emphasize "extended" followup, and greater executive emphasis.

Without such support in learning ways to manage the effects of heavy exposure we have only one choice—to repeat over and over the same mistakes, to accumulate masses of inconclusive data, and to watch thousands more workers lose their health and lives.

In the past, we had little reason to believe that we could learn new ways from the National Cancer Institute.

Dr. Gary Flamm of NCI, at the opening session of the Clearinghouse on Environmental Carcinogens on November 8, 1976, expressed the attitude of hopelessness in NCI that once prevailed:

> In the State of Michigan there are ongoing efforts to establish registries of people who are on the quarantined farms where there has been heavy exposure to polybrominated biphenyls and we are hoping that after all of us are dead and gone there will be some information that will be useful to those that succeed us 20 or 30 years from now (that) we perhaps will have some information on approximately 4,000 people as to what the effects of PBB's may be.

In a 1976 letter, Dr. Guy R. Newell, NCI's Acting Director said: "* * * certainly we are doing work in occupational carcinogenesis. What is probably missing is the risk factor—early detection—intervention-oriented approach * * *."

Nevertheless, even in the gloom of the past there have been rays of hope. NCI's eminent pathologist Umbreto Saffiotti recently wrote:

> A "new toxicology" is now developing to deal with the understanding and evaluation of the mechanisms of molecular and cellular toxicology characteristics of the effects of agents inducing self-replicating cell lesions * * *. The methods of this new toxicology have been developed, mostly in the last decade, as a result of considerable progress in many areas of basic science.

The cholestyramine success was not an accident and will not remain unique if the Congress and the administration take appropriate action.

More, the fruitfulness of interrupting disease even after it has begun to develop is found in the observation of Dr. Marvin Schneiderman of NCI, that we can expect nearly 10,000 deaths from bladder cancer each year, but that more than half of these lives might be saved by existing methods of early detection. If this observation from a distinguished scientist is even remotely close to the mark, it indicates the magnificent possibilities we have if we really set up the apparatus for early detection and pursue treatment thereafter.

The desperate need for an integrated industrial-community program aimed at early detection of preclinical disease received scant attention in the past. But if such a program either by itself or as part of a broader national health program could be administered by the apparatus now in place, it would be by good fortune. Legislation is needed to increase the certainty of a favorable outcome, to decrease our reliance on chance.

We have not created an apparatus in government or in the private sector aimed at reducing the risk of environmental exposure in the community and workplace through intervention. Some progress has been made in clinical research and the delivery of the therapeutic tools thus created. But these activities in most institutions are untied to environmental health and deal with disease essentially at the end of its development. Even if effective, based on what we now know, intervention usually will come too late to prevent the intiation of disease development for most members of high risk groups. But the process of doing what we can with what we know and simultaneously expanding our knowledge, must begin.

Whatever apparatus is created requires enlightened and aggressive leadership to achieve a community of efforts necessary to overcome the instinct for administrative pettiness and organizational chauvinism that haunts any large-scale operation.

Nevertheless, we must not neglect the problems of structure, which your bill and that of Congressman Maguire correctly address.

Your bill, Mr. Rogers, goes a long way toward adjusting the structure of the cancer program. In general, we support your proposal. There are, however, some additional ideas in Mr. Maguire's bill which we hope you will consider favorably and incorporate in the final version. We support, in H.R. 10190, language which:

One. Directs an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposures.

Two. Provides for a feasibility study to establish a national registry.

Three. Mandates the role of NCI in promoting coordination and cooperation with other agencies.

Four. Enables a program to identify and screen populations having a high risk for developing cancer because of occupational or environmental exposure in collaboration with labor and industry.

Five. Requires an oversight role for NCI regarding the quality of control over cancer-causing substances.

Six. Requires NCI to assist EPA in evaluating carcinogenicity tests performed by nongovernmental laboratories.

Seven. Mandates that the advisory board include public and scientific authorities with special knowledge of occupational or environmental cancer.

There are two other considerations which we hope the committee will adopt either by additional language in the law itself or through an expression of Congressional intent:

They are, one, that coordination with other agencies does not mean preemption and assistance does not mean maintaining a monopoly over governmental resources. Thus, we believe that the capabilities, in the control of cancer, of OSHA, NIOSH and NIEHS are essential and need to improve and expand, albeit in collaboration with NCI. An inter-agency agreement should be required which would specifically spell out the responsibilities of each agency so that the different missions of each agency are met and the separate perspectives remain.

Two, the NCI bioassay program must continue even when basic research—as distinct from testing—objectives are met, until such time as the Federal Government has developed an adequate national testing program.

Finally, although our focus at this time is cancer, we are equally concerned about disease of the heart, lung and blood. In this regard we support the language of H.R. 10908 which would add "environmental pollutants" to the list of concerns in the prevention of these diseases.

We have added some tables, four tables that I think are self explanatory and need no further discussion or description on my part.

[Tables referred to in Mr. Clayman's statement follow:]

TABLE I

Selected High Cancer Risk Populations Exposed to Single Carcinogens.
Unregulated (No Permanent OSHA Standard)

AGENT	POPULATION AT RISK
Benzene[*]	2,000,000[c]
Inorganic Arsenic	1,500,000[c]
Cutting Oils (Nitrosamines)	780,000[i]
Ethylene Dibromide	660,000[i]
Chromate Pigments	550,000[i]
Trichloroethylene (TCE)	280,000[i]
Hexavalent Chromium	175,000[c]
Acrylonitrile[1]	125,000[i]
Cadmium	100,000[c]
2-Nitropropane	100,000[i]
Epichlorohydrin	50,000[c]
Chloroform	40,000[i]
Beryllium	30,000[c]
N-phenyl-B-naphthylamine	15,000[i]
Polychlorinated Biphenyls (PCB)	12,000[i]
Hexamethylphosphorictriamide (HMPA)	5,000[i]
Dibromochloropropane (DBCP)	3,000[o]
Chloroprene	2,500[i]
4,4'-diaminodiphenylmethane (DDM)	2,500[i]
Dimethylcarbamoylchloride (DMCC)	200[i]
Exposed:	6,430,200

[c] NIOSH Criteria Document Estimate

[i] NIOSH Intelligence Alert Estimate

[o] OSHA Press Release

[*] Permanent Standard Stayed in Court

[1] Emergency Temporary Standard Stayed in Court

TABLE II

CARCINOGENS REPORTED BY NCI CLEARINGHOUSE*

Trichloroethylene
Chlordane
Aldrin
Chloroform
Tetrachlorvinphos
Procarbazine
1,1,2,2-Tetrachloroethane
Tris(2,3-Dibromopropyl)phosphate
Dapsone
Dibromochloropropane
2-Methyl-1-Nitroanthraquinone
Lasiocarpine
Captan
Hexachloroethane
4-Chloro-o-Phenylenediamine

NTA
Heptachlor
Dieldrin
Chlordecone (Kepone)
IPD
Tetrachloroethylene
1,1,2-Trichloroethane
Nitrofen
Isophosphamide
1,2-Dichloroethane
2,4-Dinitrotoluene
Trifluralin
Chloramben
4,4'-Thiodianiline
5-Azacytidine

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* Based on fifty-four NCI bioassay reports reviewed by the Data Evaluation/Risk Assessment Subgroup. Eighty-eight chemicals were tested. Due to marginal data or inadequacies of the studies, the results from tests of Proflavin and Picloram were questionable.

TABLE III

Unused NIOSH Microfilm Records of Workers Exposed to Beta-naphthylamine (BNA) and Benzidine (BZ).

Plant and Location*	Chemical	Number of Records	Period
Blackman—Uhler Chemical Division Synalloy Corporation Augusta, Georgia	BNA	262	1940-72
Blackman—Uhler Chemical Division Synalloy Corporation Spartanburg, South Carolina	BNA	804	1967-72
Lakeway Chemicals, Inc. Muskegon, Michigan	BZ	220	1962-73
Fine Chemicals Division The Upjohn Company North Haven, Connecticut	BZ	1,200	1946-63
Young Aniline Works, Inc. Baltimore, Maryland	BZ	680	1937-73
TOTAL		3,166	

*NIOSH has identified Tenneco, GAF, Fabricolor, Allied, American Aniline, Toms River and Geigy plants that once produced BNA and BZ, but have not identified the workers exposed. DuPont BZ and BNA production plants and workers unstudied.

TABLE IV

HARVARD MEDICAL SCHOOL
DEPARTMENT OF MEDICINE

PLEASE REPLY TO.
MASSACHUSETTS GENERAL HOSPITAL
PULMONARY UNIT
BOSTON, MASSACHUSETTS 02114
617-726-3733

January 18, 1977

SUMMARY OF 1976 MEDICAL SURVEY AT KBI, HAZLETON, PA.

Total number of employees	162
Total number of men surveyed	161 (one refused)
Total number of x-rays	146

Normal x-ray and lung function ____________ 121

Decreased vital capacity requiring a repeat measurement ____________ 5

Decreased vital capacity, unchanged from previous years, no follow-up ____________ 5

Abnormal x-rays requiring further x-rays or M. D. evaluation - 3

1. - 2 densities on the left - repeat PA, lateral and fluoroscopy.

2. - questionable pleural disease on the right - repeat PA, lateral, decubitus views.

3. - enlarged left ventricle - see M. D. for physical exam, B. P. check and EKG.

Abnormal x-ray report sent to us requiring the actual x-ray for our review and comparison with old films ______ 5

Abnormal lung function and x-ray requiring further evaluation at MGH ____________ 1

Obstructive lung disease requiring M. D. evaluation __ 9

Obstructive lung disease not requiring M. D. evaluation ______ 4

Normal lung function, no change in an abnormal x-ray ______ 11

No change in abnormal lung function and abnormal x-ray ______ 7

Decreased vital capacity and increased heart size requiring M D. evaluation - 1

Mr. ROGERS. Thank you very much, Mr. Clayman for a very concise statement and expressing your concerns which the committee certainly will look into.

Mr. Maguire.

Mr. MAGUIRE. It was, indeed, an eloquent statement, a humane statement, and a very wise statement, Mr. Chairman. I particularly appreciate the emphasis that Mr. Clayman has placed on acting on the basis of what we know. So often in these hearings we have quite properly appeals for more knowledge and for better research and so on, and that is critical, but I don't think often enough we focus on the need, as policymakers, to assure that people, now, today, tomorrow, next week, next year, are going to be protected to the maximum degree we can protect them on the basis of the knowledge that we already have. I think that is a theme that Mr. Clayman has expressed very, very eloquently. I also want to express my appreciation to him for coming today. As president and secretary-treasurer of the Industrial Union Department, he has enormous responsibilities. We are very grateful for his presence here before the committee today.

Mr. Clayman, you have referred, on page 6 of your statement to the fact that,

> We have not created an apparatus in government or in the private sector aimed at reducing the risk of environmental exposure in the community and workplace through intervention.

You suggested above that we need what you call an "integrated industrial-community program."

I wonder if you or Mr. Samuels might wish to expand a little on how you might see such a mechanism being put in place and operating because, frankly, we are at a bit of a loss on how to do that. I feel very strongly NCI should be given a lead role. I feel very strongly, as you do, that the other agencies ought to continue to do what they are best able to do in the particular domains of their responsibility. An outreach program is vitally necessary but also not simple to put in place, or perhaps it is simple to put in place, use our existing resources, but I would welcome an additional comment from either of you.

Mr. CLAYMAN. You have made it easy for me to refer your question to Mr. Samuels because you included him in the question, so I will ask him to make a response, and I will become his critic thereafter.

Mr. MAGUIRE. Fine. It may be something that you may want to submit some more thoughts to us later on, but if you have additional thoughts, at this time, it will be helpful.

Mr. SAMUELS. Thank you for the question, Congressman, because it is something to which we have given a great deal of thought. It is something for which any extensive comment would require an addition to the record—if you feel it is necessary. In a nutshell, what it means is that you have to look at the agency in terms of how the various elements of the agency are focusing on the problem and how these elements are interacting with other agencies.

For example, the Department of Defense is the largest single employer in the Nation. They have severe problems related to cancer, especially in the shipyards. There needs to be very close collaboration. There needs to be a transfer of knowledge, of technology, as the NCI knows it, so it can be applied to identifying, notifying and extending what medical assistance we can to the roughly 1 million workers at risk for whom the Navy has a special responsibility. That, to some degree, is occurring.

As you know, whenever you have two cabinet level agencies involved, there is always the problem of who is going to sure that each agency does its job. That kind of high level apparatus does not exist. I would think that it does need to exist, but it also needs to exist further down the line, much below the cabinet level, at the section level of the Government where things really happen. Agencies of government that don't seem to focus on these special problems need the spur of priorities and, of course, this comes from each Secretary. The language does not imply that we are suggesting a new agency, but rather a redirection of the existing agency efforts.

Mr. CLAYMAN. I suspect that part of the answer is a reeducation of the medical community in the various communities to detect these diseases. In many communities the facilities are very poor. In those areas, especially in smaller communities, where you may have indeed as much of an exposure to carcinogens as in large communities, the expertise to observe, to detect, to determine, even to report, are not there. I suspect that untold thousands are in the incipient stage of some disease and no methodology, really, or capability to make the determination in time to get the job done is available. Perhaps the medical schools—maybe you have to go down that far—medical schools need to be advised and encouraged to develop greater expertise in the area occupational diseases. But I would like to seize upon your suggestion that we develop a more carefully thought out, more specific program, to answer the question that is enormously central to the corporation of this problem.

Mr. MAGUIRE. I think we all need to think about the logistics of how we are going to reach that 7 to 8 million workers you referred to in the most efficient and timely fashion, and I would welcome a continuing dialogue on that point.

Mr. CLAYMAN. We would be happy to undertake that difficult and proper question.

Mr. MAGUIRE. You invited us, in effect, to ask about some further details respecting the Tyler, Tex., and Louisville, Ky. cases. I wonder if you would like to do that, now?

Mr. CLAYMAN. I did invite you and if you look at the record, ultimately, I suggest Mr. Samuels would be in a unique position to enlighten you.

Mr. SAMUELS. Yes, sir, these were demonstration programs. One of the key elements in developing a demonstration program is to develop, in these cases anyway, community level programs that can be replicated elsewhere. These were not community level programs that can be replicated anywhere. In Tyler, Tex., which is a not only well publicized but a tragic event even when the television cameras are turned off, millions were spent in computers, "consultants" brought into the special project center, a great deal of time and money was spent going to scientific meetings and very ineffectual—in the early years of the program virtually nonexistent—educational programs. There was a focus on the cigarette, which is certainly important, because of cancer, but not an overall approach to the kind of information that exposed workers need. There was very little real research in clinical intervention. There were a long list of problems that we saw in Tyler, and it was tragic because NCI certainly intended to do a good job. In Louisville, Ky., much of the same kinds of problems occurred. There was, in addition to that, misinformation given to these exposed workers and their families about what their risks were. Some of the testing, bioassaying of the workers themselves, from the reports that are made available to us from the National Cancer Institute, appeared to be inadequate. Our concern over these projects isn't that we had failures, because I think we have to expect failures—we can't expect success every time we try to initiate a project in a new area—but rather, that there didn't seem to be, until the appointment of Dr. Upton, any attempt to learn from these failures, go to the next project and develop some programs that were coordinated with adequate in-house technical support on which we could build a program.

Mr. MAGUIRE. Do I take it you feel the National Cancer Institute has not been sufficiently oriented toward preventive approaches in the past?

Mr. SAMUELS. Just looking at the budget, it is apparent that the concentration has been on the development of medical technology. We don't want to underemphasize the need for this. There are millions of people, if not this year, over the next generation, who will need the assistance which this technology provides. The treatment centers which were developed by NCI, in fact should become the basis—or one of the bases—for the kind of community program that Mr. Clayman refers to. We have, in effect, a network which NCI has already created which could become a source of intervention. This network is not now tuned to the environmental hazard, in part because the environmental situation has been downplayed and degraded.

Mr. CLAYMAN. I suspect that at the center of the problem is the question of the will of the total society, including government, to really get this job done.

For example, I am thinking of the experience of the British in their shipyards in the last World War. Years before we even talked about the problem, the British were aware that their shipyard workers were in trouble and it became a real problem there. They developed some devices, some compensation, some means of treatment. We waited almost until the problem exploded in front of us before we even paid heed to the British experience. The fact is that we didn't have the will to really pitch in and try to tackle this onerous job. If Congress, for example, indicates this will, and provides the funds, I think we will be able to find the apparatus to get the job done. Even though, at this moment, Congressman Maguire, we can't spell out how precisely, I think that while difficult, it is doable.

Mr. MAGUIRE. Well, thank you very much. I do appreciate your emphasis on "will". I think that is exactly right. I don't know whether you have read—I suspect you have—the book by Paul Brodeur, called "The Expendable Americans", which portrays the incredible story to find levels of exposure in one plant and the repeated decisions by government agencies that were supposedly responsible and others, which amounted to deliberately ignoring the facts as they were presented—bureaucratic inertia—elevating short-term financial considerations above other considerations, and the whole sore story—criminal neglect on the part of all concerned—and we face this again and again and again. I hope your testimony here today and the actions of this committee will help to put us on a different path.

Thank you for your generous allocation of time, Mr. Charman.

Mr. ROGERS. Dr. Carter.

Mr. CARTER. Thank you, Mr. Chairman.

Occupational carcinogenesis related to work conditions of many years ago, that is, cancer may develop years after the first exposure, in many cases. How would you recommend we act without waiting 20 years?

Mr. CLAYMAN. I suspect, what we have first got to do, is recognize that certain exposures may ultimately result in production of a cancer.

Mr. CARTER. Where are you from, please, sir?

Mr. CLAYMAN. Washington, D.C.

Mr. CARTER. Have you always lived here?

Mr. CLAYMAN. No, sir, I lived in Ohio.

Mr. CARTER. You are right in the edge of, really, a cancer area, as perhaps you know.

Mr. CLAYMAN. No question about it.

Mr. CARTER. There is much cancer in this area. What do you think causes it?

Mr. CLAYMAN. What do I think causes it?

Mr. CARTER. Yes, the cancer in this area.

Mr. CLAYMAN. In that area in Ohio?

Mr. CARTER. No, Washington, D.C., the east coast?

Mr. CLAYMAN. I am afraid, Dr. Carter, that I don't want to pose as a medical expert, but I have one beside me. Maybe he has an answer to that question.

Mr. SAMUELS. Dr. Carter, there is a concept in the literature called the Urban Gradient in Cancer—it is quite controversial and it doesn't explain all cancers for the total population. For an area like Washington, D.C., it may have some meaning because this is not a highly industrialized area, but there are some urban factors which give us reason to believe that they might be agents which lead to the trends that we experience. For example, the largest single source of pollution in the Washington, D.C., area, is the motor vehicle. Motor vehicles today, for example, use motor oil with an additive called ethylene dibromide. Ethylene dibromide has been used to chemically sterilize bulls. It is in the air we breathe. It is probably in the air in such small quantities that no epidemiologist would risk relating it to a single case of cancer because of the multiple factors that exist in an urban environment.

Mr. Carter. Over in Baltimore, there is much cancer, the cancer rate is higher, I think in the Eastern States than any group in the country. Can you account for that?

Mr. SAMUELS. If you look at the cancer map which you are referring to and look at the whole coast, not just Washington, D.C.

Mr. CARTER. Yes, we looked at the whole coast.

Mr. SAMUELS. There are quite a number of interesting variations. For example, in that part of New Jersey that is closest to the Delaware line, there are very sharp rises in the kind of cancers which are associated with occupation, such as bladder cancer. When you look closely at the death certificates, you find many of those people that develop these cancers were, in fact, workers employed by the DuPont Corp. and other corporations. In Baltimore, there is a spot of cancers that have definitely been related to a number of chemical firms. One is the Young Chemical Firm, which made benzidine, another is the FMC plant where nitrosamines were found. The occupational cancers that are reasonably linked to these occupational exposures, of course, sometimes become swallowed in the overall statistics.

Mr. CARTER. Were you ever down at the plant in Louisville, where they had cancer as a result of exposure, I believe, to polyvinyl chloride?

Mr. SAMUELS. I have only seen that plant from the outside.

Mr. CARTER. What type of cancer was that?

Mr. SAMUELS. That was Hepatic Hemangiosarcoma, cancer of the vessels in the liver—very rare. However, that cancer is only an index of the total number of cancers that seem to be appearing among not only those workers but workers exposed to polyvinyl chloride throughout the area.

Mr. CARTER. Five deaths, five suspected cancers. In that one plant, from that one type of cancer!

They have tightened the exposure to polyvinyl chloride tremendously. It seems to me where we have many manufacturing plants, particularly those which manufacture chemicals, we have an increased incidence of cancer. Is that not correct?

Mr. SAMUELS. The NCI maps do show a pretty good correlation, especially in the chemical industry.

Mr. CARTER. Particularly in the chemical industry, that is right. Thank you very kindly. How would you remedy this situation?

Mr. SAMUELS. For the people that have been exposed in the past, as our testimony indicates, Dr. Carter, OSHA and EPA regulation is certainly not adequate. The problem that we face for the worker who has been exposed over a long period of time is how to break the links in the development of the cancer.

Mr. CARTER. By the time he is exposed, it might be too late. That may come too late. The seed may have been planted and he may have cancer 20 years from now.

Mr. SAMUELS. Just a footnote to what I have said, sir. There is another important element which I hope the regulatory agencies pay attention to, that is, the heavily exposed worker who remains on the job working with that carcinogenic agent needs to have extra protection, and I know the Occupational Safety and Health Administration is attempting to do that.

Mr. CARTER. Well, we certainly think so. It is my feeling that OSHA and NIOHS view these different manufacturing plants very, very carefully.

Thank you.

Mr. ROGERS. Thank you. Let me just ask one question.

Would you favor adding the heads of the FDA, the EPA, the Labor Department, and the Consumer Product Safety Commission on the National Cancer Advisory Board? Do you think that would be a good idea to coordinate?

Mr. CLAYMAN. My quick judgment is, yes.

Mr. ROGERS. Thank you very much, Mr. Clayman and Mr. Samuels. We are very pleased to have your participation. I think you represent a very important segment of people who are affected and so I hope this will set a pattern of an even greater interest in health legislation on the part of labor. It is helpful to us to have your viewpoints expressed in testimony, so we welcome it, and are pleased that you are here today.

Mr. CLAYMAN. Mr. Chairman, I am glad you are encouraging us but even without that encouragement, we would assume that responsibility, and we shall return. One of the reasons we would like to return is this is a very pleasant committee to talk to.

Mr. ROGERS. Thank you for being here. We are grateful.

We next have a panel composed of Dr. John R. Nelson, president of the Association of Community Cancer Centers, and Grace Monaco, national liaison chairperson for Candlelighters.

We welcome each of you to the committee. Your statements will be made a part of the record in full, without objection, and you may proceed, as you desire.

STATEMENTS OF GRACE POWERS MONACO, NATIONAL LIAISON CHAIRPERSON, CANDLELIGHTERS; AND JOHN R. NELSON, M.D., PRESIDENT, COMMUNITY CANCER CENTERS

Mrs. MONACO. Dr. Nelson waived in my direction. I don't believe chivalry is dead, so I will oblige and proceed first.

We are most happy to be back addressing a committee we feel very, very at home with, because it is a committee that has paid a great deal of attention not only to the scientific basis that is necessary for good national cancer effort, but also to the observations of the people that are a part of that effort, the people that are affected by the effort, the patients and the families that have someone who is being treated or has been treated for cancer.

When we first appeared before this committee back at the beginning of the Cancer Act, we were three little parents groups in three States: Florida, California, and Washington, D.C. I think I can state now we are actually a coalition of formal and informal parents groups in 40 States, and that the product of our work over the last 1½ years is what you have before you in the statement we are making to this committee [see p. —].

We have very closely followed the way the National Cancer program has evolved and we have looked most closely into the ways that we believe that the cancer program can be improved to bring more and better results from the research effort to those who are effected with cancer, particularly those who are children and adolescents. We also bring a certain amount of good news, and, of course, good news is not considered very sexy, so I suspect the media isn't very interested, but I know this committee is very interested in it.

As of this time, about 33 percent of the children and adolescents that are diagnosed with cancer are cured of cancer. If we take a look at cancers that are treated well now, and I would say that includes leukemia, Hodgkins and lymphomas, the percentage of long-term survival and cure is in the 50 percentile and up we are talking about. I think we have come a very long way from the first time we started talking to you, and we were talking solely about the expansion of the research efforts to gain any kind of results. As of now, we are saying we see what the efforts this committee has given emphasis to have done, and we wish to assure that those efforts are distributed among all those that need them, and that the cancers that have been resistant to research innovation shall become the subject of more close examination.

I felt I was listening to myself talk from some of the remarks Mr. Maguire made. I am a transplanted New Jerseyite, who fell in with a gentleman from this area.

When Congressman Maguire stated he wanted people to act on the basis of what we know, that rang a responsive chord in two regards, both of which I will address first because they are the simpler part of what I have to talk about.

When we first appeared before the committee, we were talking about an absolute absence of information that was readily available to the frontline physician and the family and the patient with cancer. The people that wanted to know—what is a bone tumor, what is leukemia, what is lymphoma? Is there anything the Cancer Institute can give us to explain what is happening to our family member and how to cope with it. The information dissemination programs that were made a part of the 1971 act, expanded on in the 1974 act, have paid off. Cancer information services give parents and family and physicians access to good information on the state of the art of cancer treatment. We have ready to go to press now—I say, we—I have such an identity with them—they have 24 pamphlets ready to go to press that are updates of all of the pediatric cancer literature as well as some new things we haven't seen before. The one gap that exists in the program now is not the results of their efforts, but rather an absence of statutory direction, and I would like to see added to the information dissemination language in the statute an emphasis also on the dissemination of information relating to rehabilitation. As we have more and more patients that are survivors, the survivors have special problems and those problems need to have greater emphasis in the information dissemination effort.

Our statutory language suggestions are set forth as a separate appendix to our statement.

The other remark that Mr. Maguire made was with respect to a feasibility study, and a national registry. I think that that certainly is a most needed component of our cancer program, and I would suggest and point to your attention pages 4 and 5 of our statement, in which we specifically ask for a national childhood and adolescent cancer registry. This we will explore later because it fits into the three-pronged approach we would like to see, but I would also point out, before we go into that, that the children are only 1 percent of the cancers, and that they have proved themselves to be the demonstration point, the laboratory, so to speak, for the development of most of the innovations that we see now in adult cancers, the combined chemotherapy and the like which pioneered in pediatric cancer, and then was translated into the adult cancers.

If we want to see how the registry can work, we can look at pediatric concertresearch that has led the way.

I also would like to mention the nutrition program. In 1974, when we came before this committee, we pointed out there seemed to be a great deal of information floating around on nutrition but no one knew where it was and what to do with it. The word nutrition evoked unscientific responses from the scientific community. Candlelighters asked what is the relationship, if any, between nutrition and diet and cancer. This committee listened carefully to that, and the day we testified, in fact, Dr. Rauscher, who was director of NCI was sitting in the audience and Chairman Rogers questioned him on our suggestions. Dr. Rauscher had to agree that we were not off base, there should be something done and something was done by this committee in the diet, nutrition, and cancer program. That program, I have to say, is still a bit of a stepchild because the scientists are not terribly convinced that the word, nutrition, doesn't call up witches and warlocks, but I think that the progress that has come out of that program so far justifies a continued emphasis by this committee. That is a prevention program. It is a program that is looking at the cause and prevention of cancer from a nutritional basis, if there be any, as well as treatment. It will give us the answer from a scientific and reliable perspective as well as the aspect of it that we first looked at, which is: How can better nutrition serve our children to fight against the ravages of their diseases and of chemotherapy and surgery? There are some good answers that have emerged. There are booklets to help families. That is the easy part of what I have to say to you—nutrition and information dissemination.

Now, I will get to the new approach to the research of childhood cancer that we would like to see. A three-pronged approach to the research effort into pediatrics and adolescent cancers that will involve, (1) The establishment of comprehensive cancer centers, five in number, plus the one at the NIH Clinical Center, combined with, (2) an extension of the already excellent Division of Cancer Control and Rehabilitation Outreach programs, their leukemia and lymphoma network that reaches down to the community physicians and gives them the aid and assistance they need tied to a center of excellence in childhood cancer to draw from for specialized assistance, specialized equipment, evaluation and reevaluation, so more and more of our children can move from the cancer center to the community complex for treatment. I think we see more and more children, through the efforts and demonstration, that DCRR has put together, that are being treated successfully in the community setting. I have statistics relating to that in my testimony, and (3) a maternal childhood and adolescent cancer registry.

There is one troublesome aspect that results from, more children being treated where they should be treated in the community, the numbers that we need for a research effort. We have come up with some marvelous ways of treating children with leukemia and lymphoma. We have also come up with some treatments that have extraordinarily toxic side effects which reach down the corridors of their lives, if they are survivors, and which deal with the type of prevention effort Congressman Maguire focused on. These survivors may develop secondary tumors from treatment and other problems we cannot now conceive of. These numbers are lost to us as far as a research effort is concerned, if they are treated in a community hospital setting. They are not part of a retrievable data base. We want to see the researchers refine the treatment our children are getting so we will have less toxic side effects as more and more treatments move out of the center and into the community. We can't do that unless we have a sufficient accrual of numbers to be able to follow those children. That is why we ask for a national registry and that the cost of entering children into that registry be part of the federally funded cancer research.

I have talked about outreach—that is working very nicely. I have talked about a registry—we feel it is necessary to prevent or detect early cancers in children who have been subject to radiation and chemotherapy but why are we asking for a designation or establishment of additional centers for the study and research into adolescent and childhood cancers. I wish we didn't have to ask. When you first established the comprehensive centers in the 1971 act, embellished in the 1974 act, we hoped those centers could be the centers of excellence for all cancers. Unfortunately, the small numbers of pediatric cancers get lost in the comprehensive centers with very few exceptions. The research innovations that have occurred in pediatric and adolescent cancers have come out of those places that concentrate on pediatric cancer, and for this reason, as a matter of commonsense, and for easier management and continuation and expansion of excellence in the whole pediatric research area, we are asking for the special designation or establishment of cancer centers dealing with childhood and adolescent cancer.

That is the story from us this afternoon.

[Testimony resumes on p. 352.]

[Mrs. Monaco's prepared statement and attachments follow:]

STATEMENT OF THE CANDLELIGHTERS
ON THE "BIOMEDICAL RESEARCH AND RESEARCH TRAINING AMENDMENTS of 1978 (H.R. 10908)
BEFORE THE
SUBCOMMITTEE ON HEALTH AND ENVIRONMENT
OF THE
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE
OF THE
UNITED STATES HOUSE OF REPRESENTATIVES

Mr. Chairman and Members of the Committee:

My name is Grace Powers Monaco; I am representing CANDLELIGHTERS, a national coalition of families of children affected by cancer in 40 states. We wish to bring to your attention those areas in which federal funding has had the most noticeable impact on our children's lives and those which we feel merit your further attention either through program re-direction, emphasis or increased funding levels or position allocation.

Let me first extend on behalf of all of us our deep gratitude and appreciation to you, Mr. Chairman, and the members of this Committee for your continuing efforts on behalf of all persons afflicated with cancer. Your unflagging interest in cancer research and the translation of this research into tangible programs for detection, treatment and rehabilitation of cancer victims throughout the country has widened the benefits of the whole cancer effort. We know that the lives of our children have been and are continually being extended, and in many cases preserved, through the cancer research efforts which this Committee has supported through the National Cancer Institute.

Our testimony on H.R. 10908 focuses upon: the establishment of Comprehensive Cancer Centers for the Research of Childhood and Adolescent Cancers; the establishment of a National Comprehensive Cancer Registry for Childhood and Adolescent cancers in support of the national research effort; cancer control, specifically the outreach programs for the demonstration of successful methods of treating childhood and adolescent cancers; nutrition and cancer and the information dissemination role of the National Cancer Institute. Attached as Appendix A hereto are drafts of the specific statutory language requested by CANDLELIGHTERS for the proposed revision of the authorization for the National Cancer Institute.

Further, Appendix B hereto contains CANDLELIGHTERS recommendations as to appropriations levels for the basic Institute program and for cancer control for fiscal 1979 through 1981. CANDLELIGHTERS beleives that the authorization levels set in H.R. 10908 should be increased to provide the appropriations committees with flexibility in responding to the needs of the Institute as they evolve.

THE NEED FOR COMPREHENSIVE CANCER CENTERS FOR CHILDHOOD AND ADOLESCENT CANCERS AND FOR A NATIONAL COMPREHENSIVE CHILDHOOD AND ADOLESCENT CANCER REGISTRY IN SUPPORT OF THE RESEARCH EFFORT

CANDLELIGHTERS request for the specific establishment or designation of Comprehensive Cancer Centers for research into Childhood and Adolescent cancers and the clinical application of that research together with an expansion of outreach programs to the community based physician and a supporting National Registry has as its objectives:

(1) To encourage a more effective advancement in the biomedical and behavioral sciences by focusing upon innovative, creative investigation in Childhood and Adolescent Cancer.

(2) To develop through investigation, curative treatment for this patient population which would not include compromising either the quality of life or their individual basic human rights as research subjects and as minors.

(3) To "extend survival with disease" by "curing" more children and adolescents more efficiently.

Through our unique vantage point as grass roots participants in the National Cancer Institute's clinical investigation efforts, we have observed and experienced both the rewards and the problems in the current research and demonstration programs which affect the cancer-stricken children and families. These observations, detailed below, provide the genesis of CANDLELIGHTERS proposal.

Childhood cancer research has proved to be the single most effective model for understanding and treating many forms of cancer. Developments in childhood cancer have been successfully applied to adult cancers. Pediatric cancers pioneered combined modality therapy utilizing surgery, radiotherapy and chemotherapy, various rescue factor approaches and adjuvant chemotherapy which have effectively arrested or retarded the development of many adult cancers. Dr. Emil J. Freireich of the University of Texas System Cancer Center in Houston has said that drug combinations pioneered in pediatric cancers are now producing remissions in a majority of adults with acute myelogenous leukemia and a "proportion of these patients are being cured. Five years ago if you asked me if we were producing cures, I could only say, 'rarely'." Additional specific examples include the development of and use of antifols in childhood leukemia which led to curative measures in adult cancers, specifically the use of antifols in women with choriocarcinoma; adjuvant chemotherapy in breast cancer to prevent metastases; and, the combination chemotherapy in acute lymphocytic leukemia which is now being used successfully in adult Hodgkins disease, finally the total thereapy concept used for childhood ALL is now being used successfully in cooperative study clinical trials involving adult lung cancers.

These applications of the results of research in pediatric and adolescent cancers underscores the importance of preserving, expanding and building upon the research efforts committed to childhood and adolesecent cancers.

Observations by parents in a variety of treatment settings suggest that this research effort can best be served by Comprehensive Cancer Research Centers for childhood and adolescent cancers.

Although the inclusion of a pediatric oncology center in an adult institution need not necessarily thwart development, our conversations with noted oncologists,-pediatric and otherwise-, confirm that the Comprehensive Cancer Centers authorized by this Committee are almost exclusively oriented toward the adult cancers.

Childhood and adolescent cancers present differently, may have different causes, also respond differently from the adult cancers. The research breakthroughs in pediatric cancer therapy have largely originated from centers specifically devoted to pediatric cancer. Further, the apparently prevailing view in these centers is that pediatric cancer is a small percentage of cancers, and thus shouldn't receive the attention or program status that adult cancers receive.

The need for a nationwide, coordinated approach to childhood and adolescent cancers arises from:

(a) A need to insure that all children with cancer have access to effective diagnostic and treatment modalities.

CANDLELIGHTERS of Metropolitan Washington surveyed its members on the problems of diagnoses. The results, drawn from 54 case histories, showed that 61 percent of the cases, involving 13 types of cancer, were accurately diagnosed within 16 days. But diagnosis for the remaining 39 percent took anywhere from 16 days to a year.

The Chairman of the American Academy of Pediatrics Neoplastic Disease Committee, Dr. Frederic Silverman, confirms that "any given pediatrician in the course of his 30 or 35 years of practice is only going to see a few cases of actual cancer. Consequently, he's not in a position to deal with it unless he can get some real help and get to the experts in the field."

(b) The need to develop less toxic therapies to avoid adverse complications in children with cancers which can now be successfully treated.

> "For the longevity of life, we paid dearly. He lived for a long time (7years) but the results of his living with this disease caused extensive damage to

> his lungs and cataracts in his eyes. The children are living longer, but the drugs are still as toxic as ever. It becomes a serious question of the deterioration in the quality of life" - Annandale, Va. mother of a 10 year old son recently deceased from acute leukemia.

(c) A need for sufficient accrual of child cancer experience in certain cancer categories, which have been resistant to therapy, and require increasing research attention.

(d) A need to follow meticulously the long term effects including tetragenic, carcinogenic, mutagenic, neurological and long and short term risks in pediatric and adolescent cancer treatment (survivors).

These latter needs arise from a welcome phenomenon. Children with leukemia, lymphoma or hodgkins disease may now be treated adequately in a community hospital setting. Demonstration outreach programs in community hospitals and pediatric oncologists treating children in a multi-center study funded by the NCI Division of Cancer Control and Rehabilitation (Children's Hospital, Los Angeles; Children's Hpspital, Cincinnati; Children's Hospital, Denver; Dartmouth Medical School; University of Alabama; New York-Cornell; Mount Sinai School of Medicine) have clearly established, using a children's hospital as an evaluation and re-evaluation center, that in excess of 50% of these children will probably attain a five year survival.

However, since pediatric malignancies are much less common than adult cancers (1%) and since children treated in community hospitals are not generally included in research studies, the ability to follow and utilize them as research subjects in developing less toxic therapy and in following long term effects of childhood cancer is clearly diminished. This problem for research innovation and treatment will increase as more and more pediatric cancers, thru DCCR's demonstration programs, move into community hospitals for treatment. Since childhood cancer is the model for the study and understanding of all tumor types, these falling patient accrual rates pose a threat to the entire cancer research efforts.

For all these reasons, it is recommended that there be established or designated regional comprehensive cancer research centers for children and adolescents, including the clinical cencer at NIH. It is further recommended that the research effort at these designated centers be supported by the establishment, supervisor, and utilization of a nationwide Comprehensive Childhood Cancer Registry through the Division of Cancer Treatment at the National Cancer Institute.

This goal is realistic and workable: Almost 4800 of the anticipated 6400 new pediatric cancer cases each year in the U.S.A., are accessible to a data retrieval system through their inclusion in one of the childrens cancer study groups or existing pediatric comprehensive centers. Research programs and the community based or children's hospital based cancer control programs may make the remainder accessible.

The Childhood and Adolescent Cancer Comprehensive Centers would serve as the focal point of a government financed effort in pediatric cancer research and its clinical application, i.e., these centers would serve as a diagnostic reference point and an available resource for re-evaluation and long term follow-up for all pediatric cancer patients. These centers, by management and use of this large and varied research data system, could more quickly pinpoint deadends or promising beginnings in research and clinical trials, and thus speed refinement, improvement and change in pediatric cancer management.

One model suggested for this National Registry is the "Delaware Valley Pediatric Oncology Program and Central Tumor Registry" which is a Division of Cancer Control and Rehabiliatation program originating from Children's Hospital in Philadelphia under the direction of Dr. Audrey Evans.

The bottom line for this CANDLELIGHTERS proposal is finding the research and outreach climate that will not merely reverse the disease but will cure the child. This goal is not beyond our reach. At a National Conference on the Lymphomas and the Leukemias, in October of 1977, the term "cure" was used repeatedly by researchers. 30 years ago the average survival rate for children witb acute lymphocytic leukemia (ALL) was only two months. Now for 50%, it is five years, with many living and well far longer.

When former childhood leukemia patients live long enough to have their own families and normal lives, "it is splitting hairs not to call them cured", said Dr. David J. Galton of the Royal Postgraduate Medical School, London, England. "We are possibly beginning to see the same upswing in other forms of cancer".

Dr. Joseph V. Simone of Stanford University and Dr. Donald Pinkel of Milwaukee Children's Hospital told of a group of more than 100 children with ALL who are in remissions, apparently well, three to ten years after drug treatment was stopped. "I think they are fairly safe now." Dr. Simone said.

Dr. Charles M. Huguley, Jr. of Emory University said, "you get different results if you treat in expectation of cure rather than palliation. Once we realized we were really curing Hodgkin's diseases, the cure rate zoomed up."

We are also seeing a similar pattern developing in several other cancers of children and young adults such as primary bone sarcoma. Not enough time has elapsed to be able to give long-term survival figures, but the early pattern is so similar to the one we saw in ALL that I hope in a few years to be able to give equally good news about them, These recommendations by CANDLELIGHTERS hold the promise of more good news.

DIET AND NUTRITION IN CANCER

At the request of CANDLELIGHTERS, the Diet, Nutrition and Cancer Program (DNCP) of the National Cancer Institute was mandated by Congress in 1974. At that time amendments were introduced to Sec. 407 (b) (4) of the National Cancer Act of 1971 which now authorizes the National Cancer Program to:

> "collect, analyze, and disseminate information (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer) useful in the prevention, diagnosis and treatment of cancer..."

Up to the end of 1977, 31 projects have been initiated and a range of educational and informational docuemnts has been developed. The program has established itself with the medical and scientific communities. This has been done with the funding and staffing that fall short of receommendations and requests, and that are very low in relation to the importance of nutrition in cancer prevention and treatment, and of the expected cost effectiveness of nutrition research.

The DNCP informally coordinates its research activities with NIH programs as well as other government agencies. During 1976 and 1977, the NIH Nutrition Coordinating Committee (NCC) emerged as a trans-NIH entity for overall coordination of nutrition activities. It is likely that the NCC will develop an operational coordinating function during the next few years. At that time, the activities of the Diet, Nutrition and Cancer Program will be integrated in an overall set of NIH priorities in nutrition.

Some of the projects completed are nutritional handbooks, for both adults and pediatric cancer patients; Review and Analysis of Categorical Citation Information relevant to the DNCP; Literature Study on Indicators of Health and Nutritional Status with Emphasis on Primitive populations; Literature Study to Evaluate Health parameters in various human populations in relation to diet.

Some ongoing projects include: Identification of Past, Ongoing, and future dietary and nutritional surveys and Cancer Epidemiology studies; Development of a guidebook for inclusion of Dietary and Amnthropometric Parameters in cancer epidemiology studies; survey of Dietetic Practices and Procedures used in feeding cancer patients; Evaluation of the role of Learned food aversion in the cancer patient; Gustatory (taste) evaluation of cancer patients; Anorexia in Adult and Pediatric cancer patients; Optimal Nutritional support as an adjunct to cancer therapy in the pediatric patient; studies of differential nutritional requirements by Host and tumor as the basis for dietary treatment of cancer (brain tumors); Optimal Nutritional support as an adjunct to cancer therapy in the adult; Environmental Stress and Tumorigenesis; Nutritive quality of dietary fiber for humans; dietary components and cancer development; effect of nutritional and environmental stress on carcinogenesis; effect on nutritional stress on carcinogenesis.

Some of the new programs include: Dietary patterns, nutritional assessment, and cancer incidence of american vegetarians; Quantification of changes in body composition in cancer patients and evaluation of pharmacologic agents for the treatment of anorexia in the cancer patient.

These programs speak from a scientific basis to the questions which American public asks on the relationship of diet and nutrition to the cause, prevention and treatment of cancer. We specifically request that authorization of this program be retained. Levels of appropriations which appear to be needed to support this program are 10 million in fiscal 1979, 12 million in fiscal 1980, 16million in 1981.

INFORMATION DISSEMINATION

The Office of Cancer Communications has initiated a variety of programs including a Clearinghouse and Cancer Information Services through the Centers to implement the mandate of the 1974 Act to devise means to interpret and disseminate new and existing knowledge and information produced by the cancer program to researchers, practicing physicians and the general public. The demands on this office by the scientific and lay public are great. CANDLELIGHTERS can attest to the value of the information services provided and their usefulness to parents and front line physicians. They are indeed bridging the information gap. Due to the efforts of this office, all of the site specific pamphlets on pediatric cancer have been updated and new ones have been added. However, there is one omission in the current statutory language which should be remedied. The cancer "family" or patient also needs information on rehabilitation, the key, among other things -, to a successful re-entry into the community. For this reason CANDLELIGHTERS requests that the statute extend the Institute's information dissemination role to include and the rehabiliation of the cancer patient including in the latter term information relating to employability, insurability, education, physical therapy, psycho-social support, and the long term effects of cancer therapy in surviving cancer.

We also request that six additional positions be assigned to the dissemination effort.

Mr. Chairman, Members of the Committee, on behalf of all parents across the country, I should like to again commend you for your efforts and for your understanding of our problems. Your dedication to the cause, the cure and the prevention of cancer encourages us to face the future with a greater degree of hope and peace of mind. Those of us who have lost children are grateful that your efforts to authorize the cancer research that will be a memorial to them. And those of us whose children are under treatment are grateful for the hope which research gives in maintaining their well-being.

We gratefully acknowledge the part this Committee has played in the effort to conquer this dreaded disease. Thank you for permitting ys to appear before you.

APPENDIX A

CHILDHOOD AND ADOLESCENT CANCER CENTERS; COMPREHENSIVE CHILDHOOD AND ADOLESCENT CANCER REGISTRY

SEC. 408 A. National Cancer Research and Demonstration Centers for Childhood and Adolescent Cancers;

National Comprehensive Childhood and Adolescent Cancer Registry

(a) Authorization; Support for Centers. The Director of the National Cancer Institute is authorized to provide for the establishment or designation of six centers (including the pediatric and adolescent oncology unit at The National Institutes of Health Clinical Center) for clinical research, training and demonstration of advanced preventive, diagnostic, treatment and rehabilitative methods relating to Childhood and Adolescent cancers. Such centers may be supported under subsection (c) of this section or under any other applicable provision of law.

(b) Authorization; Support for National Comprehensive Childhood and Adolescent Cancer Registry . The Director of the National Cancer Institute is authorized to provide for the establishment of a National Comprehensive Childhood and Adolescent Cancer Registry. Such registry will be established and managed by the Division of Cancer Treatment of the National Cancer Institute. Such registry may be supported under subsection (c) of this section or under any other applicable provision of law.

(c) Cooperative agreement with nonprofit agencies or institutions for federal payments of basic operating support; uses of federal funds; support limitations; periods and extensions of support. The Director of the National Cancer Institute, under policies established by the Director of the National Institutes of Health and after consultation with the National Cancer Advisory Board, is authorized to enter into cooperative agreements with public or private nonprofit agencies or institutions to pay all or part of the cost of planning, establishing, or strenghtening, and providing basic operating support for existing or new centers (including, but not limited to, centers established under section (a) of this section) for clinical research, training and demonstration of advanced prevention, diagnostic, treatment and rehabilitation methods relating to childhood and adolescent cancers. Federal payments under this subsection in support of such cooperative agreements may be used for (1) construction (nothwithstanding any limitation under section 285 of this title); (2) Staffing and other basic operating costs, including such patient care costs including transportation and living expenses for a child or adolescent and family member as are required for research and also including the costs of entering and maintaining each child or adolescent with cancer nationally in the Comprehensive Registry under subsection (b) of this section; (3) Clinical training (including clinical training for allied professionals), and (4)demonstration purposes; but support under this subsection (other than support for construction) shall not exceed $5,000,000 per year per center. Support of a center under this section may be for a period of not to exceed three years and may be extended by the Director of the National Cancer Institute for additional periods of not more than three years each, after review of the operations of such center by an appropriate scientific review group established by the Director of the National Cancer Institute.

Information

410 (G) (1) The Director of the National Cancer Institute shall provide and contract for a program to disseminate and interpret on a current basis, for practitioners and other health professionals, scientists, and the general public, scientific and other information respecting the cause, prevention, diagnosis and treatment of cancer, and the rehabilitation of the cancer patient including in the latter term information relating to employability, insurability, education, physical therapy, psycho-social support, and the long term effects of cancer therapy in surviving cancer patients.

Nutrition

407 (4) Collect, analyze; and disseminate information (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer) and expand, intensify and coordinate existing research programs within the National Cancer Institute relating to the role of diet and nutrition in the prevention, diagnosis and treatment of cancer...

APPENDIX B

Authorization for Appropriations

Section 409 (b) is amended by striking out "and" after "1977" and by inserting before the period the following: $94,000,000 for the fiscal year ending September 30, 1979, $96,000,000 for the fiscal year ending September 30,1980, and $99,000,000 for the fiscal year ending September 30, 1981.

Section 410 C is amended by striking out "and" after "1977"; and by inserting before the period the following: $975,000,000 for the fiscal year ending September 30, 1979; $1,075,000 for the fiscal year ending September 30, 1980; and $1,175,000 for the fiscal year ending September 30, 1981."

Mr. ROGERS. Thank you. It is an excellent story, too, and very helpful, and we are delighted to have you back before the committee again.

Dr. NELSON.

STATEMENT OF JOHN R. NELSON, M.D.

Dr. NELSON. Mr. Chairman, and members of the committee, my name is John R. Nelson. I am a practicing physician specializing in surgical oncology in Jacksonville, Fla. and am currently president of the Association of Community Cancer Centers. I am pleased to present this testimony on behalf of the Association.

The association is composed of physicians, nurses, hospital administrators, and other health care personnel interested in providing better cancer care to the patients in our Nation's communities. Our membership represents over 400 community institutions responsible for the 35 percent of cancer patients who need more specialized care than that available in most American College of Surgeons-approved general-care hospitals. Yes less specialized than that provided in comprehensive cancer centers. This means that roughly 100,000 new cancer patients are treated by our facilities each year.

We understand that the subcommittee is currently considering a 3-year renewal of the National Cancer Act. In its deliberations, we would hope the subcommittee would consider the major work that needs to be, and can be, accomplished in the next 3 years.

Allow me to begin my comments by emphasizing that the community health care providers in the association believe your decisions in 1971 and in 1974 to initiate and renew the National Cancer Act have greatly benefited the cancer patients in this nation's communities. Many of the new treatment techniques now available in the communities and in specialized and comprehensive cancer centers offer new hope, longer survivals, some cures, and a better chance for a more productive life for our patients. We hope you will consider renewing the act for a 3-year period at an early date, allowing the National Cancer Institute to continue its excellent work with maximum continuity.

When considering the authorization legislation before you, we hope you will consider several factors.

First, there are several projects under consideration by the National Cancer Institute which we believe are urgent and which deserve additional monies above current funding projections. A second generation of drugs that are less toxic and more effective is a high priority for community cancer care. If these drugs become available, it will make a major difference in our treatment of patients and in their physical and mental well-being during treatment. This proposal well deserves a $15-million addition to current projections.

A second set of NCI proposals directly impact upon members of our organization. We need a source for continual up-to-date education on new treatment methods for our patients. The comprehensive cancer centers, with scientists involved in the latest patient research, are our best source of this type of information. We hope Congress will continue to support the current centers, consider creating new ones, and designate specific appropriations for cancer control programs from cancer centers in its new budget. Our patients and your constituents deserve the best care available.

The National Cancer Institute's Cancer Control Division has developed many programs that we, in part, have carried out through centers or networks. However, these are erratic, with budget shifts frequently interrupting education efforts. Community physicians want continuous information or tend to regard a program as resembling RMP, that is, uncertain wether their participation will be abruptly ended when the program is terminated. This discourages many providers from becoming involved in cancer education efforts. By regularizing community education programs through centers, and by specifying dollars for that purpose, the Congress can insure that information will quickly and regularly get to the public and the professions. We hope the subcommittee will consider authorizing up to $20 million to be utilized at the 19 comprehensive cancer centers to bring this educational information to us.

As a matter of information input, I called Dr. Gordon Zubrod, who is the comprehensive cancer center director in my area yesterday, and discussed this proposal with him. He indicated to me that practically all of the Florida center's dollars that provide information dissemination to the community have been utilized. He indicated money is not available for the outreach programs in the Florida area and indeed in the Southeast.

I have talked also with Drs. John Durant, William Singleton and others in my area, so I am quite knowledgeable and in contact with these key people in comprehensive cancer center community outreach efforts.

The National Cancer Institute is also proposing the establishment of an additional 20 "total community cancer" programs at some $200,000 each. We would suggest that the need for an additional level of sophistication between those hospitals meeting the American College of Surgeons' standards and the designated centers is far greater. At least 35 percent of cancer patients need more sophisticated care. Only 10 to 15 percent can or should be seen in centers. The additional 25 to 30 percent possibly 35 percent can receive the best possible treatment closer to home and family in their own communities. Our member institutions provide much of this care currently, but money to organize their community efforts is lacking. We would hope the subcommittee would consider authorizing sufficient monies to establish 400 of these minicancer centers throughout the country, meeting the more extensive standards established by the Association of Community Cancer Centers. At $200,000 per program, this $80 million, one-time expenditure, would bring quality cancer care to many more people.

A third set of NCI priorities which the association hopes the subcommittee will authorize deal with pain control and the development of terminal care facilities. The need for more research in the types of pain and the means by which it may be ameliorated is great. The association is especially interested in the concept of "hospice." The association believes that the concept of hospice is a major addition to community cancer care. We believe that the activities and efforts extended by quality hospice programs have an appropriate place and role in the care of the terminally ill cancer patient and should, therefore, receive the support of the medical and allied health professions not only for their humanitarian social worth but for their contribution in reducing the potential catastrophic economic impact upon the individual and the family. Since there are several emerging "models" of hospice—community-based, hospital-based, and free standing—we hope the subcommittee will authorize sufficient funds to demonstrate all of these models. We would suggest that Congress authorize at least 12 demonstration efforts at $500,000 each or $6 million for the demonstration of hospice models.

The association also believes that the role of community cancer care providers should be recognized in the national cancer program and in your renewal of the act. The community health care provider is the ultimate recipient of much of the information on better treatment for cancer patients. NCI and the National Cancer Advisory Board need community input. We recommend the Subcommittee amend section 410B(a) of the National Cancer Act, designating 2 of the 18 National Cancer Advisory Board members as "community Cancer care providers actively engaged in the treatment of cancer patients." This will insure solid community input into NCI's outreach efforts.

Currently the 18 member National Cancer Advisory Board is appointed without any specific representation. However, we note that in this renewal of the act you are already considering designating 3 of the members as "knowledgeable in environmental carcinogenesis." With over $60 million designated for community programs, the NCAB has no representatives from the practicing medical community. We would hope the subcommittee would end this exclusion.

Mr. Chairman and members of the subcommittee, I hope these recommendations by the Association of Community Cancer Centers are of assistance during your deliberations. Our interest is in providing quality cancer care in our communities. Your support for the National Cancer Act, the NCI and an increased level of authorization is urged. Now, as we begin to see the results of the last 6 years, is not the time to slow down a good program.

I might also interject, as did Dr. Byrd, yesterday, that I am a practicing physician. I am not funded by NCI, and most of my efforts are volunteer.

Mr. ROGERS. And the committee commends you, Dr. Nelson, and appreciates your service and also the statement you have given to us today.

Dr. NELSON. Thank you, Mr. Chairman.

Mr. ROGERS. Dr. Carter.

Mr. CARTER. Thank you, Mr. Chairman.

Do you think that the work that you are doing should be expanded rather greatly, the 400 centers, such as you are a part of now?

Dr. NELSON. Dr. Carter, I believe that the taxpayers dollar can be most effectively utilized by taking existing community cancer care programs and developing them into what we would call mini-centers or what we would refer to as ACCC accredited cancer care programs. That way, we would not be spending money to duplicate facilities already in communities.

In Jacksonville, Fla., we have had a cancer registry in existence for almost 20 years, where information is available and where we are studying what has happened to our cancer patients. We have all of the facilities one would expect. It would be a loss and a waste of funds to inject too much money into that type of situation. However, we are in great need of money to help coordinate cancer care activities in Jacksonville. We have what is called the northeast Florida cancer program and we have a secretary who tries to coordinate all the various activities, but she is funded with a very small number of dollars. This needs to be improved. We have this type of situation in varying stages of sophistication throughout the country. Some hospitals have a hundred beds, some 500. The level of the cancer care program in each of these hospitals varies. We feel 35 percent of these programs should be upgraded to an accredited status.

Probably 50 percent of other hospitals can handle basic cancer care without too much sophistication. Many cancers can be handled effectively without a sophisticated cancer program. We do not propose the use of dollars under those circumstances, when they might best be utilized elsewhere. The community is fully supportive of the sophisticated center. We think research, education, and treatment go hand in glove.

Mr. CARTER. How would you like to settle that—with medical school being the center? They could coordinate an outreach program in different sections of the state? Of course, the school can be used and specialists at the school can be used to assist them out in the areas of the State—do you like that idea or not?

Dr. NELSON. I think I would support that idea, and I think that, as I have worked in the Association of Community Cancer Centers since 1972, I see the need for consideration of community needs in different sections of the country. I do not think that a master program can be applied to the entire country. By so doing, we would waste the efforts that have been expended by universities, by clinics and by specialized and comprehensive centers. An example would be Dr. John Durant's program. Another would be Dr. Moertel's program at the Mayo Clinic. Across the northern section of our country, he has proved that evaluation and treatment of some cancers can best be clinically studied at the community level.

Mr. CARTER. Dr. Martell?

Dr. NELSON. Dr. Moertel.

Mr. CARTER. That is a different Moertel than the one who has done some work on radioactivity of alpha particles causing cancer?

Dr. NELSON. Dr. Moertel is head of the section dealing with gastrointestinal cancer.

Mr. CARTER. What success have you had in the treatment of Leukemias?

Dr. NELSON. I do not treat Leukemias personally.

Mr. CARTER. Do you often use chemotherapy or X-ray before you do your surgery?

Dr. NELSON. I do not often use X-ray prior to surgery. Chemotherapy is frequently used, particularly in breast cancer.

Mr. **Carter.** There is a difference of opinions between surgeons in this area. Some feel they should and others don't. Certainly, I support your program.

Dr. **Nelson.** Thank you very much.

Mr. **Carter.** Continue to do so.

Mr. **Rogers.** Mr. Maguire.

Mr. **Maguire.** Thank you. Mr. Chairman.

I would like to ask the two of you whether you feel there has been enough emphasis on preventive strategies at NCI in the past and whether you would advocate expanding and intensifying efforts based on disirability of preventing cancer?

Dr. **Nelson.** I think that NCI, through their Division of Cancer Control, has been very helpful to the community. We have worked with Dr. Fink and the various people in her Division. We believe that more effective control can be accomplished at the community level through satisfactory funding of community cancer centers.

Mr. **Maguire.** When you use the word, control, does that signify prevention, in your mind?

Dr. **Nelson.** Yes.

Mr. **Maguire.** Or——

Dr. **Nelson.** I think the control of cancer is prevention. I think that if one is able to detect cancer cause and effect preventive measures, that does represent cancer control.

Mr. **Maguire.** The word, prevention, doesn't appear anywhere in your statement. Your entire statement, as I understand it, is oriented toward the treatment strategy.

Dr. **Nelson.** I think you can appreciate the fact that we are a group of community providers and as such our patients are in need of treatment. As I listened to testimony this morning, I heard the very excellent presentation of the scientists who necessarily have to look down the road 10, 15, 20 years, 30 years. I have to look at today and tomorrow.

I got up at 4 this morning and made rounds in three hospitals and saw many cancer patients in varying stages of treatment. Their needs are today and tomorrow. Consequently, most of my efforts are in the direction of community cancer treatment.

Mrs. **Monaco.** I think I would also like to address that. We have, in our statutory appendix, and I think at various points throughout our statement, mentioned prevention—the nutrition program we support. We have also mentioned it in the context of adding prevention in the——

Mr. **Maguire.** I didn't say you hadn't mentioned it?

Mrs. **Monaco.** I know you didn't, but I might tell you, maybe it sounds a little unusual coming from the mother of a child with cancer—when you are dealing with treatment, as something that can keep your child with you—but our organization is thinking not just of our experience, but the other parents we hope will be able to avoid the experience we have had, if we can have means of prevention of cancer and for this reason, in the pediatric cancer area, I could commend to you the program of Dr. Robert Miller at NCI. He is one of their chief epidemiologists. He puts out a little news letter each month on childhood cancer, and it is amazing the variety of things they are looking into as preventive agents in the womb and after that—biological markers by which you will be able to tell if someone is developing something and stop it before it starts.

I think, in this whole area you were going into in prevention, one of the most important aspects you can concentrate on is ways of identifying by biological markers that will let us find out what is happening early enough to prevent, so we can determine when someone is approaching a problem. Things like Dr. Mike Sporn is doing at NCI, which is so helpful, we hope, in preventing asbestos related cancers. As parents, we want to prevent, and we are some of the first up in arms when an industrial plant is doing things we think are a no-no in our community. If our children already have cancer, we don't want to have that intensified, and we want to keep the rest of our family around if possible.

Dr. NELSON. One other thing, on the control situation. You are probably aware that the incidence of lung cancer in northeast Florida, is one of the highest in the country, if not the highest. We are presently, as a community cancer program, looking into why this situation exists, and if you ask me—why do we have more lung cancer in northeast Florida than any place in the country? My answer is, I do not know. We are in the process of developing a proposal to study those reasons, and I suppose that this represents community cancer control effort through our program.

Mr. MAGUIRE. Just one final question, Mr. Chairman.

Mrs. Monaco, we have discussed here a national registry which would apply to everybody. Would I be save in assuming you would not be adverse to the establishment of such a registry in that it would also include children, just as it would include everyone else?

Mrs. MONACO. I would not be adverse, if it is broad enough in scope and quality to follow the problems of survivors and side effects.

Mr. MAGUIRE. Fine. Now, with respect to centers, if it could be shown that children would get proper and adequate attention in the context of existing centers, would you feel that—would you modify your proposal? It strikes me this proposal comes out of a feeling of neglect and if the problem could be dealt with without setting up a whole new chain of centers, I wonder if that wouldn't be as good. Do you feel your proposal is really essential to changing the situation?

Mrs. MONACO. I do not have a closed mind, but it is rather close to being closed. I think we do have a few areas of excellence in this country in pediatric cancer, which are already designated as comprehensive centers. But in order to reproduce those within the centers that have been dealing primarily with adult cancer, you would really have to redesign the wheel, reinvent the wheel.

Mr. MAGUIRE. You, yourself, pointed out the relationship of what you are finding out about the child cancer and applications to adult cancer.

Mrs. MONACO. I would be happy for them to use everything to help them out we could find. I see nothing from what has happened in the last 6 years in centers that would lead me to believe that childhood cancer can, as only 1 percent of the cancers that are looked at, be anything but stepchildren in the existing centers.

Mr. Rogers. Mr. Walgren.

Mr. Walgren. Have we talked about hospices and explored the opinions of the witnesses about what should be done?

Mr. Rogers. We have gotten some expression. Is there any further comment you would like to make?

Mrs. Monaco. The question of hospices related to pediatric cancer and adolescent cancer is really not terriby fruitful. Most of the parents that have children with cancer would prefer to have them die at home and would like the ability to do that. I would hope that any hospice program that is funded would also provide for home care programs so you can have outreach from the hospice to help families have their children die at home.

Mr. Walgren. Is it my understanding there is almost no hospice type medical reimbursement at present and someone who wants to pursue that concept has a great deal of difficulty, either finding a place or having his costs covered by medical insurance?

Dr. Nelson. That is correct.

At this time, it is very difficult to finance any type of hospice activity, whether it is in the hospital or whether it is a hospice without walls, as she has mentioned in dealing with children and adults at home. We have under investigation, now, as a subcommittee of the Association of Community Cancer Centers, this very subject. That is, providing third-party payment for a hospice care. We have a conference scheduled for April 28 and 29 on the subject of hospice, and at that conference the funding of the hospice will be discussed in detail; and I have several people who now are looking into mechanisms for payment of hospice activity.

Mr. Walgren. Presently, there is no funding whatsoever?

Dr. Nelson. No, not to any extent.

Mr. Walgren. Can you just quickly sketch out for me these various models that you recommend pursuing?

Dr. Nelson. Basically, there are three models. One would be the freestanding hospice. That is a hospice that is built for the terminal care patient whose restrictive guidelines are considerably different than you would experience in normal hospitals. That is, there would be no hour of exclusion of family or friends. There would be no prevention of the patient receiving medicines, during pain, nausea, vomiting. It would be developed with a number of paraprofessionals; that is, people involved in the social and economic wellbeing of the terminal cancer patient, the clergy, and so forth. There is a total concept of hospice care under that concept. We also see a second hospice model being developed in community hospitals. Under these circumstances there is the same type of approach, but with hospital activity. We have recommended the nurses in that type of unit not be floating about the hospital but be trained in the care of the terminal patient. A third type of hospice model is being developed to help take care of the terminal cancer patient in the home with physicians and nurses and social workers participating in that care along with the appropriate church and clergy.

That, briefly, represents the three models we are interested in developing.

Mr. **Walgren.** As someone who sees a great deal of cancer patients, would you say that the hospice concept deserves a high priority in our medical funding system from government sources?

Dr. **Nelson.** Yes; I think it deserves a high priority when you consider over half of the patients with cancer are going to die of that disease. Their terminal care becomes very important. Particularly, the extension of their life with radiation, surgery, and chemotherapy is probably making hospice care even more important because they are going to live longer and deserve more care during the terminal phase of their illness.

Mr. **Walgren.** Is it true that there would be circumstances where somebody would have need to be admitted to a hospital to die and not be covered by present insurance systems because they are not going to be receiving "skilled nursing care"?

Dr. **Nelson.** That is entirely possible. I saw a lady this morning who is a patient of mine, who 5½ years ago had extensive breast cancer involving the artery, lungs, bones. She had chemotherapy and she is alive 5½ years later. She is in the hospital now because in the little town where she lives, she does not have any type of care facility. After a certain number of days she will be subject to peer review in my hospital, and no longer be authorized for continuing payments of her care. She will be subject to being placed in a skilled nursing facility. She will be reviewed in that facility by the peer review mechanism of my medical society, and if it is determined she does not need skilled care, she may not, in fact, have funds available for her care. That is just one example of what is going on right now in community hospitals.

Mr. **Walgren.** So there are severe gaps when someone comes to a terminal situation in the care we are talking about?

Dr. **Nelson.** Yes, and I can readily see this same patient, the same example being duplicated—I am sure that patient can receive better care for less money in a hospice situation.

Mr. **Walgren.** Thank you.

Mr. **Rogers.** We are grateful to each of you for being here. Your testimony has been most helpful and we congratulate Candlelighters on their growth in this country. It has performed a very important service for members and the Nation.

Dr. Nelson, we are glad to hear of the progress being made in Florida and tying in the network.

Thank you for being here.

The committee will stand adjourned until 10 a.m. tomorrow morning.

[Whereupon, at 3:45 p.m., the subcommittee adjourned to reconvene at 10 a.m., Friday, March 3, 1978.]

BIOMEDICAL RESEARCH AND RESEARCH TRAINING AMENDMENTS OF 1978

FRIDAY, MARCH 3, 1978

House of Representatives,
Subcommittee on Health and the Environment,
Committee on Interstate and Foreign Commerce,
Washington, D.C.

The subcommittee met pursuant to notice, at 10 a.m., in room 2218, Rayburn House Office Building, Hon. Andrew Maguire, presiding [Hon. Paul G. Rogers, chairman].

Mr. Maguire. The subcommittee will come to order.

We will continue, today, our hearings on the biomedical research and research training amendments of 1978, H.R. 10908, H.R. 110190, and similar identical bills.

The first panel of witnesses includes: Dr. William Barclay, Editor, Journal of the American Medical Association; Mr. Robert K. Dresing, vice president, The Cystic Fibrosis Foundation.

Gentlemen, will you come to the table, please? Dr. Barclay, would you like to begin, sir?

STATEMENTS OF WILLIAM R. BARCLAY, M.D., CHAIRMAN, COMMITTEE ON GOVERNMENT REGULATIONS, AMERICAN LUNG ASSOCIATION; AND ROBERT K. DRESING, VICE PRESIDENT, CYSTIC FIBROSIS FOUNDATION, ACCOMPANIED BY GIULIO J. BARBERO, M.D., MEMBER

Dr. Barclay. Mr. Chairman, I am William R. Barclay, and I serve as the editor of the Journal of American Medical Association. I also serve on the board of directors of the American Lung Association and as chairman of its Committee on Government Relations.

I appreciate this opportunity to present to you the recommendations of the American Lung Association and its medical section, the American Thoracic Society, on H.R. 10908.

In the interest of saving time, I will summarize the detailed recommendations of the American Lung Association, which are enclosed and will be submitted, for the record [p. 364].

Emphysema, chronic bronchitis, asthma, and related diseases rank today as the fifth leading cause of death from disease, and unfortunately we still do not know the complete story of how to prevent them. Together, mortality from these diseases is larger than that from diabetes, or from cirrhsis, or from arterisclerosis.

Disability benefit payments for workers forced to retire prematurely because of emphysema are in excess of one-half of a billion dollars, according to the Social Security Administration. We know that there are certain genetic factors involved in the development of some kinds of emphysema. So to some extent it might be an inherited disease.

Cigarette smoking is certainly involved and is especially dangerous in the presence of certain substances in the workplace environment, and even in the general environment. With the advent of a strong pulmonary program in NHLBI, new disciplines are being brought to bear on the study of the pathogenesis of emphysema, which some day will provide the answer we need to control this debilitating and life-threatening condition.

There is no organ of the body more assaulted by the environment or by occupational hazards than the lung. Our highly technological society and the growing recognition of the threat of occupationally induced disease makes it urgent to study how the pulmonary system reacts to industrial agents and environmental pollutants.

In the long run, occupational disability can be prevented only through a more complete knowledge about the types of lung injuries caused by these agents and how they bring about disease.

Although several other institutes and Federal agencies are involved with applied aspects of occupational pulmonary disease research, the activities of the Division of Lung Disease are vital to bring forth the fundamental knowledge of the biology of the lung and its diseases and that knowledge can only come from basic research. This basic knowledge is necessary to achieve the goals of applied research and prevention.

Thus, the reasons for a vital and expanded research program in lung disease are compelling. Human suffering and medical care costs, economic loss due to compensation, forced retirement and premature death, make it mandatory for this country to accord pulmonary disease research the degree of financial support which is commensurate with the problem these diseases represent.

Operating on a current budget of slightly more than $60 million, the Lung Division is witnessing an extraordinary growth of interest in pulmonary disease which reflects the widespread prevalence of these diseases and our need to know more about them. It must be in a position to exploit these research opportunities.

In 1977, the Lung Division was forced to turn down onehalf of its approved research applications because of the lack of funds. Frompresent trends, it appears that the percentage of approved grants which will not be funded will be even higher than in fiscal 1978. I might say that the Lung Division has experienced an increasing number of grant applications, but the percentage of those not approved before of increased costs has also risen.

Our recommendations are that we wish to request a 3-year authorization for the National Heart, Lung and Blood Institute at a level which will provide the Division of Lung Diseases at least $90 million for fiscal 1979 of which $76 million would be for extramural research.

We believe a budget of $90 million is necessary to allow maximum implementation of the Division's program for controlling such diseases as emphysema, asthma, certain pulmonary diseases which are fatal to newborn infants and other equally serious diseases.

Under present law this amount of support would require an authorization of $600 million to the National Heart, Lung and Blood Institute. We regard a 3-three renewal of authority as essential to rational planning. Our recommendations for the next 3 years are in our record submission, and they are: $600 million for fiscal year 1979; $690 million for fiscal year 1,980, tnd $795 million for fiscal year 1981.

The National Heart, Lung and Blood Institute has had 16 percent of the total NIH resources for a decade, with no proportional increase for the additional missions mandated in recent years by Congress. In view of the tremendous disease burdens for which the Institute has responsibilities, we believe that our recommendation for an increased ceiling of $600 million in 1979 is justifiable. A dynamic pulmonary program is dependent on the level of dollar authorization.

The fact that the commitments of the Division of Lung Disease for 1979 amount to $55 million, and that only $5 million will be available for new initiatives, illustrates the great need for more funds for pulmonary disease research. Representatives of the pulmonary disease community are convinced that $90 million in research funds is urgently needed for the Division of Lung Disease if we are to move toward control of respiratory diseases, a major cause of mortality and morbidity in the United States.

Thank you, sir.

[Testimony resumes on p. 370.]

[Mr. Barclay's prepared statement follows:]

Statement of the American Lung Association
H.R. 10908, the Biomedical Research & Research Training Amendments of 1978
to the Subcommittee on Health and the Environment
Committee on Interstate and Foreign Commerce
U.S. House of Representatives
March 1, 1978

It is a pleasure for the American Lung Association to support re-authorization of the National Heart, Lung, and Blood Institute through renewal and extension of the National Heart, Lung, and Blood Act. That Institute is the ALA's major point of contact with NIH in relation to the chronic pulmonary disease problem.

We wish to request a three-year authorization of NHLBI at a level which will provide the Division of Lung Diseases at least $90 million for fiscal 1979 of which $76 million would be for extramural research. We believe a budget of $90 million is necessary to allow maximum implementation of the Division's program for controlling such diseases as emphysema, asthma, certain pulmonary diseases which are fatal to newborn infants and other equally serious diseases. Under present law this amount of support would require an authorization for NHLBI of $600 million. We regard a three-year renewal of authority as essential to rational planning; our recommendations for the next three years are as follows:

	(in millions)		
	total	research	prevention & control
fiscal 1979	$600	$565	$35
fiscal 1980	690	650	40
fiscal 1981	795	750	45

Pulmonary Disease Research

The Division of Lung Diseases was established in 1972 as a result of the expansion of the National Heart Institute in late 1969 to encompass a major pulmonary program. These actions were evidence of the growing recognition of the threat of chronic respiratory diseases. For a decade ALA had voiced concern about the precipitous increase in mortality from emphysema and other obstructive lung diseases and the fact that there was no focus on these conditions within the federal research establishment. It was with great expectations, therefore, that ALA welcomed the new Division. Our hopes have been substantively realized.

Beginning with a minimal program, the Division's efforts have led to the development of strong and active scientific leadership in pulmonary medicine. There has been a 100 percent increase in research applications in pulmonary medicine to NHLBI just within the last year, and the quality of applications is high. This degree of vigor is essential to unraveling the mysteries of pulmonary disease, but it must be sustained by adequate financial support if it is to be productive. There has been a sharp climb in unfunded but highly meritorious research applications and a concomitant enlargement of research opportunity lost by insufficient fiscal resources.

Due in great degree to research supported by the Division since 1972, we now know that the solution to preventing or alleviating many serious lung diseases may well lie in expanded knowledge about the structure of the lung and its mechanisms of functioning, as well as in better understanding of the disease processes themselves.

Remarkable progress has been made in basic areas of pulmonary physiology--we understand more about the complexity of the respiratory control mechanism; the chemical and cellular composition of the lung; the synthesis, secretion, and effect of surfactant, a substance which regulates surface tension of the lung (and a major factor in infant mortality). This new knowledge provides the groundwork for advances that are directly relevant to specific disease categories although the initial approach is to basic mechanisms. Because of this new knowledge, pulmonary disease research is on the threshold of major explorations not before possible.

Emphysema, chronic bronchitis, asthma, and related diseases rank today as the fifth cause of death from disease, and we still do not know the complete story of how to prevent them. Together, mortality from these diseases is larger than that from diabetes, or from cirrhosis, or from arteriosclerosis. Disability benefit payments for workers forced to retire prematurely because of emphysema are in excess of half a billion dollars, according to the Social Security Administration. We know that there are genetic factors involved in the development of some kinds of emphysema. Cigarette smoking is certainly involved and is especially dangerous in the presence of certain substances in the workplace environment. With the advent of a strong pulmonary program in NHLBI, new disciplines are being brought to bear on the study of the pathogenesis of emphysema which someday will provide the answers we need to control this debilitating and life threatening condition.

However, the impact of pulmonary disease does not only fall on adults. Both our organization and the Division of Lung Diseases have given high priority to pediatric lung disease. Asthma affects millions of children. In addition to the need for more information on the cause of such diseases, there is a need to know whether adult pulmonary diseases develop as a result of childhood respiratory conditions. In addition to research in asthma, cystic fibrosis, and bronchiolitis, the Division's activities include work in respiratory distress syndrome which still causes excessive infant mortality in spite of considerable advances in diagnosis and treatment.

Respiratory failure is another important area for continuing exploration. It occurs not only in persons with respiratory disease but many whose lungs fail as a consequence of trauma--surgery, accidents, aspiration, drug overdose, etc. Respiratory failure is much more prevalent than reported and affects persons of all ages, including healthy young adults. In spite of improvements in diagnosis, monitoring and treatment, a better understanding of the mechanisms of lung injury and repair is needed. Research supported by the Division of Lung Diseases has now pinpointed certain avenues of research which appear promising and which need a comprehensive program of collaboration among clinicians, epidemiologists, pathologists, and other basic scientists. The Division is currently instituting such a program in the Specialized Centers of Research (SCOR) to study the development of respiratory failure.

There is no organ of the body more assaulted by environmental or occupational hazards than the lung. Our highly technological society and the growing recognition of the threat of occupationally induced disease makes it urgent to study how the pulmonary system reacts to industrial agents and environmental pollutants. In the long run, occupational disability can be prevented only through more complete knowledge about the types of lung injuries caused by specific agents and how these occur. Although several other Institutes and federal agencies are involved with applied aspects of occupational pulmonary disease research, the activities of the Division of Lung Diseases are vital to bring forth the fundamental knowledge of the biology of the lung and its diseases that comes only from basic research. This basic knowledge is necessary to achieve the goals of applied research and prevention.

Thus, the reasons for a vital and expanded program in lung disease are compelling. Human suffering and medical care costs, economic loss due to compensation, forced retirement, and premature death, make it mandatory for this country to accord pulmonary disease research the degree of financial support which is commensurate with the problem these diseases represent. Operating on a current budget of slightly more than $60 million, the Division is witnessing an extraordinary growth of interest in pulmonary disease which reflects the widespread prevalence of these diseases and the need to know more about them; it must be in a position to exploit these research opportunities rather than be forced to turn down half of its approved research applications because of lack of funds, as occurred in 1977. From present trends, it appears that the percentage of approved grants which are not funded will be even higher in fiscal 1978.

Education

The 1977 report of the Task Force on Prevention, Control, and Education in Respiratory Disease emphasizes the large role for education of the physician as well as the individual. Our success in changing certain health-related beliefs, attitudes of individuals, communities, health professionals, industries and government agencies--is essential to progress in respiratory disease control. For instance, programs to discourage smoking especially by those predisposed to risk should have the highest priority; millions of Americans continue to smoke. We know that many airborne organic or inorganic dusts, aerosols or gases are specific causes of respiratory disease and that inhalation of these substances can be prevented. Another example is education of hospital personnel about the need to delay deliveries and Caesarians until the fetal lung has reached maturity; this is basic to more progress in avoiding hyaline membrane disease in infants. It is our hope that as a result of the Task Force's impressive report, Congress will see fit to appropriate money for educational activities such as these.

Justification

ALA feels justified in requesting $90 million for the pulmonary program not only because of the evidence of need that cannot presently be fulfilled but because our organization is qualified to assess the needs of the Division of Lung Diseases. Our own program objectives are closely allied with those of the Division. For instance, the Lung Division is the leading component of NIH which supports cessation of smoking. Because the Division has a broad perspective of the total importance of cigarette smoking in relation to health, we think that funds for any new federal initiative in this direction should be closely coordinated with the program of the Division of Lung Diseases. Again, the Division supports more pediatric lung research than does any other Institute. Certainly in emphysema, chronic bronchitis, and the obstructive lung diseases, the Division is the leader in research. All of these are program priorities of our organization and consequently we are familiar with and capable of evaluating the Division's research effort in them.

We would like to bring to the Committee's attention the fact that both the Division and ALA have worked for reduction of medical costs where this is consistent with quality care. ALA leadership has always considered this a responsibility and considers it especially important today when soaring medical costs are a national concern.

Some years ago, ALA initiated steps to encourage the closing of tuberculosis sanatoria because chemotherapy had made it possible to treat patients more effectively on a short-term basis in general hospitals and in the outpatient setting. This policy was strongly resisted in many areas but the campaign eventually led to widespread changes in medical care which resulted in tremendous savings.

More recently, our organization, through its medical section, the American Thoracic Society, has become concerned that certain procedures used in the treatment of patients with chronic obstructive lung disease, especially positive pressure breathing, needed evaluation. The ATS is currently discouraging the widespread use of this procedure unless there are specific indications in favor of it. Our organization continues to play an important role in evaluating instruments used to screen patients for pulmonary disease and in keeping expensive equipment from being used indiscriminately where productivity of case finding is low. Many of these activities are coordinated with those of the Division of Lung Diseases.

Nor has the American Lung Association hesitated to speak out against occupational compensation programs in which awards are made without adequate consideration of scientific criteria. There can be no doubt that there is a wide range of occupational disease for which society must assume responsibility. The ALA is committed not only to prevention of occupational pulmonary disease but to its adequate management when diagnosed. Part of adequate management is surely equitable compensation. However, a disease cannot be diagnosed in the absence of medical criteria.

Thus, we believe that our request for a high level of support for the Division of Lung Diseases should be viewed in the light of our organization's reputation for sound judgement and responsible action.

Training

The recent two-year and one-year re-authorization of the National Heart, Lung, and Blood Act and the Biomedical Research Extension Act are detrimental to continuity of purpose and to any economies that can be realized when funding at a specified level can be considered a realistic possibility. Lead time is especially important for institutional training programs where a traineeship often must be approved by the institution as much as one and a half years in advance of its initiation. We would also emphasize that in contrast to institutional fellowships, it is almost impossible for the individual fellowship program to achieve funding for three years, a necessary duration of training for the career-minded basic researcher.

It is our opinion that at least $25 million should be available for NHLBI training through the National Research Service Awards in 1979. It is our hope that the authorized ceiling for the NRSA program will be at a level to allow this amount of allocation to NHLBI. There is still a considerable shortage of trained pulmonary disease specialists who can serve as consultants in medical centers and as teachers of medical students. Continuation of the pulmonary training program of NHLBI is essential to solving this shortage.

Conclusion

NHLBI has had 16 percent of total NIH resources for a decade, with no proportional increase for the additional missions mandated in recent years by Congress. In view of the tremendous disease burdens for which the Institute has responsibilities, we believe our recommendation for an increased ceiling to $600 million in 1979 is justifiable. A dynamic pulmonary program is dependent on this level of dollar authorization.

The fact that commitments of the Division of Lung Diseases for 1979 amount to $55 million and that only $5 million will be available for new initiatives illustrates the great need for more funds for pulmonary disease research. Representatives of the pulmonary disease community are convinced that $90 million is urgently needed for the Division of Lung Diseases if we are to move toward control of respiratory diseases, a major cause of mortality and morbidity in the U.S.

Mr. MAGUIRE. Thank you, Dr. Barclay.
Mr. Dresing, would you proceed?

STATEMENT OF ROBERT K. DRESING

Mr. DRESING. Good morning, Mr. Chairman. I am accompanied this morning by Dr. Giulio Barbero, who is also a member of the foundation, to talk to you in support of the recommendations of H.R. 10908.

In the interest of time, and because we have submitted for the record, in writing, our specific recommendations for the continuation of the bills, and the increased authorizations, I would like, if I could, to digress from the written material slightly, and talk to you specifically about the disease of cystic fibrosis, and the impact that it has on the country [see p. 372].

By way of further introduction, I am also a 42-year-old parent of an 11-year-old son. My son has cystic fibrosis. If I were to discover today that I have lived half of my life, I certainly could accept that. However, my son who is 11, statistics tell us that as of right now he has already exceeded one-half of his life expectation. I am having great difficulty in accepting that.

I believe that there are some things that are happening with the foundation and in our research that provides us with special opportunities that we might be able to take advantage of right now. This is a special time in the history of the foundation, and we believe that what is happening with the extension could be very significant in helping us to reach some of the goals that we have been striving for, for so long.

Cystic fibrosis is still the most common, lethal cause of mortality in the United States in the caucasian population. We still have 10 million carriers that are unidentified, and for which we have no test to identify. These carriers are parenting between 1,500 and 2,500 new babies each year.

The cost of just maintenance of this population, which is ever increasing, is getting to the point where we really have to look at what are the factors on maintenance of these children, if we continue in the present programs that we have, versus what would happen to the total dollars that are being expended if we were able to increase the amount of research and come up with some answers that might substantially reduce the dreadfulness of the disease, or give us a control.

Dr. Barbero is a more scientific expert, and I would like to ask him to give us some of the aspects of the severity of the disease and the impact on our program.

Dr. BARBERO. Mr. Maguire, I have been a center director funded by the foundation right now in the rural area, looking after children with cystic fibrosis. I am also an ex-chairman of the Medical and Scientific Council of the Cystic Fibrosis Foundation.

Most recently, I had the opportunity to do two interesting looksees at what might be going on in this field with some telescopic vision, being a just rotated member of the Advisory Council of the National Institute of Heart, Lung and Blood Institute, and also funded by that Institute and the Institute of Arthritis, Metabolism and Digestive Diseases.

I have been a cochairman of a careful study which should be put out in about April, that looks at what we might do around this problem.

I think that some of the key points that are emerging are: First that this disease is moving into adulthood. It was always thought as being a childhood disease. Now we have to instruct the individuals in adult medicine, at least have them pick up the banner of advocacy and research in this disease, and that is a whole new ball game.

This has brought in a lot of new talent, but also new needs.

The second thing is that clearly the cost is becoming so great, as Mr. Dresing mentioned, that we are talking between $10 and $15 million a year, as the various studies have shown, just to maintain some kind of quality of life that is so poor that one wonders about its validity and viability.

Therefore, the cost of this not only in fiscal terms but in human terms is exceedingly serious. Thereby, the need for a more preventive approach is clearly indicated. This is in our testimony.

This is a time when a number of cures have opened up. We now have a number of animal models for this disease. We are now able to demonstrate a variety of cystic fibrosis factors. We look forward to a new plateau.

There is a need for a new infusion of people in the program that will in some way enhance and make notch in this dreadful problem. It is for this reason, I think, that our recommendations come.

I think that I want to mention something about the 3-year support versus the 1-year. It is almost impossible to plan any effective research without having some period of time, and it is equally impossible to expect trainees to make a commitment that such research requires, without having a research time period of some support, without having to struggle through on a year-to-year basis.

It is with those ends that our recommendations support the three-year extension.

Last of all, I think that our report has opened up a whole new concept that we hope to propose. Namely, our research enhancement program for the institutes, and also a cysic fibrosis program.

It is clear that the kind of tissue that needs to be generated from children which are the hardest in part, those children that do die, to attain in various specific forms, need a kind of coordination program, the kind of bank program that does not exist, and for which there have been no resources thus far.

Similarly, we now know that approximately one-third of the cystics are not diagnosed. The problem there is getting out in geographic way, not only the translation of the diagnostic features, but also making a difference in the way we understand the research implementation of some of the knowledge.

For this reason, we support very strongly this notion, and we do this also in our report to Congress which will be coming on the research on cystic fibrosis program.

[Testimony resumes on p. 384.]

[Recommendations of Cystic Fibrosis Foundation follow:]

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National Chairman
National Sports Chairman
Miss Teenage America
National Teen Chairwoman
[illegible]

RECOMMENDATIONS

The Cystic Fibrosis Foundation makes the following recommendations to the Subcommittee:

- The Foundation concurs with the three year renewal period for the National Heart, Lung and Blood Institute as proposed in H.R. 10908.
- The Foundation recommends an increase in authorizations of appropriations for the National Heart, Lung and Blood Institute to the levels recommended by the NHLBI Advisory Council.
- The Foundation concurs with the three year renewal period for the National Research Service Award Program as proposed in H.R. 10908.
- The Foundation concurs with the increase in the levels of authorizations of appropriations for the National Research Service Award Program as proposed in H.R. 10908.
- The Foundation urges a substantial increase in support of research activity to pursue the control and the ultimate prevention of Cystic Fibrosis via the following mechanisms:
  - Cystic Fibrosis Resources Program
  - Cystic Fibrosis Research Enhancement Program
  - NIH Management Plan

We deeply appreciate the opportunity to testify on the Biomedical Research and Research Training Amendments of 1978, H.R. 10908. Our comments are directed primarily to the sections of the bill concerned with the extension of authorizations of appropriations for the National Heart, Lung and Blood Institute (NHLBI) and the National Research Service Award Program.

CYSTIC FIBROSIS: MAGNITUDE OF THE PROBLEM

Cystic Fibrosis (CF) is the most common lethal inherited disorder in the Caucasian population. An estimated 10,000,000 Americans are asymptomatic carriers of the gene which causes Cystic Fibrosis. There is presently no method for identifying carriers. These carriers parent between 1,500 and 2,200 new cases of Cystic Fibrosis per year in the U.S. and current prevalence estimates range upward from 13,000 to 30,000 cases of the disease.

Cystic Fibrosis is believed to be caused by an inborn error of metabolism which brings about a complex combination of pathologies:

- Thickened mucous secretions obstruct passageways of the lungs, pancreas, liver, intestines and other sites.
- Repeated episodes of lung infection slowly destroy the lungs and lead to respiratory failure.
- The slow, relentless destruction of the lung tissues tends to place a serious burden on the heart so that heart failure may occur.
- Obstruction of the pancreas leads to a loss of digestive enzymes and the resultant nutritional problems affect growth and development.

- Excessive loss of salt in the sweat may result in heat prostration and stroke.

- Other complications such as chronic sinusitis, focal biliary cirrhosis, diabetes mellitus and male sterility can become serious problems for the Cystic Fibrosis patient.

The notion that Cystic Fibrosis is merely a children's disease is a myth. Increasing numbers of Cystic Fibrosis patients are surviving into their teens and twenties. On the other hand, about half of the children with Cystic Fibrosis die before reaching the age of twenty. In all cases the disease is ultimately fatal.

CYSTIC FIBROSIS: THE COSTS

Annual expenditures by a person with Cystic Fibrosis are extremely high. Average annual costs for a patient in relatively good health are estimated to be $10,500, with some individual expenditures as high as $50,000 to $100,000 during the terminal years. Considering that there are presently between 13,000 and 30,000 patients with Cystic Fibrosis, it is calculated that the national financial burden of caring for Cystic Fibrosis patients will fall between $200,000,000 and $600,000,000 in 1977. By the year 1985, it is estimated that there will be between 20,000 and 40,000 patients with Cystic Fibrosis. Correspondingly, the costs of Cystic Fibrosis patient care may rise to a figure between $300,000,000 and $800,000,000 annually. It should be noted that these figures represent only direct patient care charges and do not include indirect care expenses or socioeconomic costs due to early death, unemployment or underemployment.

NATIONAL HEART, LUNG AND BLOOD INSTITUTE

The National Heart, Lung and Blood Institute, through its Division of Lung Diseases, is involved in research activities of the greatest importance to our efforts to help provide solutions to the devastating lung problems which cripple young children in this country. The Foundation is extremely pleased that the proposals before the Subcommittee call for a renewal period of three years for the National Heart, Lung and Blood Institute. This will provide stability and promote continuing effectiveness of biomedical research growth and development. This extension will permit Congress to re-evaluate the progress of programs at the end of continued, stable support which, in our opinion, is an ideal process to formulate effective recommendations for succeeding years.

It is painfully obvious that authorization levels for the eight Institutes (including the National Heart, Lung and Blood Institute) at the National Institutes of Health fall far below the resources needed to implement current opportunities. It is imperative that dollars be authorized which will permit sufficient funding to provide for new initiation in meritorious program areas, as well as provide continued funding of present programs of merit at levels which take into account current inflationary rates.

Your proposed legislation provides authorizations of appropriations of $40 million for fiscal year 1979, $45 million for fiscal year 1980, and $50 million for fiscal year 1981 for prevention and control programs under section 414 of the Public Health Service Act. It also provides authorizations of appropriations of $460 million for fiscal year 1979, $505 million for fiscal year 1980, and $550 million for fiscal year 1981 under section 419 of the Public Health Service Act for the research and other programs supported by the National Heart, Lung and Blood Institute, excluding training. We appreciate the competition among Federal programs for limited dollars, however, we concur with the recommendations of the National Heart, Lung and Blood Advisory Council and urge the following authorizations for NHLBI programs in the amounts below. These funding levels would provide critical support for promising opportunities in pulmonary research in Cystic Fibrosis.

Prevention and Control Programs

FY'79	$50 million
FY'80	$75 million
FY'81	$100 million

Research and other purposes, excluding training

FY'79	$565,200,000
FY'80	$672,210,000
FY'81	$754,290,000

NATIONAL RESEARCH SERVICE AWARD PROGRAM

The National Research Service Award Program is the only vehicle through which the NIH can support research training activities. The research training activities of the NIH are crucial to the success of Cystic Fibrosis related research efforts. The availability of adequate numbers of well trained, qualified investigators to conduct Cystic Fibrosis related research is most important to finding a control for this chronic and catastrophic disorder. The Foundation is pleased that this proposal will be supportive of not only Individual Training Grants but Institutional

Training Grants as well. Institutional Grants are critical to attracting and training more clinicians in multi-disciplinary research in areas such as Cystic Fibrosis. The Foundation totally supports a three year extension of the National Research Service Award Program as well as the levels of authorizations of appropriations delineated in H.R. 10908.

THE NATIONAL INSTITUTES OF HEALTH-CYSTIC FIBROSIS FOUNDATION STUDIES: STATE-OF-THE-ART AND FUTURE DIRECTIONS IN CYSTIC FIBROSIS

The National Institute of Arthritis, Metabolism and Digestive Diseases and the National Heart, Lung and Blood Institute are co-sponsoring a study of the state of the art and future directions in Cystic Fibrosis requested in the FY 1977 Labor - Health, Education, and Welfare Appropriations bill report. This Study is being carrided out by the Cystic Fibrosis Foundation, under contract with the National Institutes of Health and will be delivered to the NIH in April of this year.

Because it was necessary to restrict this study to areas considered to be within the mission of the NIH, i.e., research, research training and technology transfer, the Cystic Fibrosis Foundation saw a critical need to prepare a companion report to address physical and psychosocial management of patients, training of health professionals, consumer education and information, economics and finance, ethics and health care delivery environments as well as research. This report will be delivered by the Cystic Fibrosis Foundation to Congress in April.

CYSTIC FIBROSIS: REPORT HIGHLIGHTS

Several points will be contained in the Foundations report which bear highlighting:

- The prospect of preventing or controlling Cystic Fibrosis would be greatly enhanced if a major commitment to Cystic Fibrosis related basic and clinical research was undertaken.

- Progress in improving Cystic Fibrosis clinical management is not likely to occur without a major commitment to both basic and clinical research.

- Until the basic defect of Cystic Fibrosis is understood or a specific marker is found, identification of the carriers of the gene and diagnosis of Cystic Fibrosis in the unborn child will not be possible. Therefore, support for research in this area is a high priority.

- To eliminate or delay Cystic Fibrosis lung and heart failure, research on the prevention, development and treatment of respiratory disease in Cystic Fibrosis is needed.

- In order to prevent the complications which develop in many organ systems in Cystic Fibrosis patients, more knowledge of the secretory process and production of mucus is needed.

- The Cystic Fibrosis patient suffers from a basic nutritional problem. Support is needed to develop a better understanding of the mechanisms and treatment of this problem.

- In a field which is constantly changing and providing exciting and unexpected research opportunities, flexible support must be available to take advantage of these new leads.

- Cystic Fibrosis research is being conducted in a number of laboratories across the country which are isolated from one another. These individual efforts, although important in themselves, would be much more effective if research environments were created to bring together a critical mass of patients, clinicians, investigators, specialized resources, etc.

- Materials for Cystic Fibrosis research are needed (e.g., animal models, tissue cultures, specimen banks, etc.)

- There is a dearth of suitably trained scientists and investigators in many disciplines important to Cystic Fibrosis.

- It is important to have knowledge of the natural history of a disease. To obtain such data in Cystic Fibrosis, standard techniques of measuring and evaluating patients are critical.

CYSTIC FIBROSIS: MEETING RESEARCH NEEDS

In order to meet Cystic Fibrosis research needs and to take advantage of opportunities to control or prevent this dreaded disease, we propose several recommendations that could be included in H.R. 10908, "The Biomedical Research and Research Training Amendments of 1978".

- Cystic Fibrosis Research Enhancement Program (REP). That there be authorized new funding levels to direct the National Institutes of Health to establish a Cystic Fibrosis Research Enhancement Program (REP) to support promising areas of Cystic Fibrosis related research. This research should be directed at both basic and clinical efforts and should focus on Cystic Fibrosis. Major Research Enchancement Program areas are:

  - Respiratory Disease in Cystic Fibrosis.
  - Metabolic defects in Cystic Fibrosis and the search for markers.

- The secretory process in Cystic Fibrosis.
- Digestive and nutritional problems in Cystic Fibrosis.
- Standardization of tests used in diagnosing and evaluating Cystic Fibrosis patients.
- Other key opportunities identified by the scientific community.

Suggested Funding:

- Year 1: $5-6,000,000
- Year 2: $6-7,000,000
- Year 3: $7-8,000,000

The establishment of this program would greatly advance research in Cystic Fibrosis for we recognize that the key to control and eventual prevention of this disease lies in the areas of intensive, dedicated scientific investigation. By providing the necessary funds for research, we will be able to support the environment and activities that are so vital to attracting the interests and attention of capable investigators.

- Cystic Fibrosis Resources Program. That there be authorized new funding levels to direct the National Institute of Arthritis, Metabolism and Digestive Diseases to create a Cystic Fibrosis Resources Program to include:
  - The establishment of six (6) Cystic Fibrosis Centers for research, professional education and translation activities.
  - The development of animal model(s) for CF research.

- The development of repositories and distribution points for specialized research resources such as cell cultures, specimen banks, etc.
- The development of focal points for clinical trials.
- The expansion of a patient registry and data base.
- The establishment of a Cystic Fibrosis publication service.

Suggested Funding:

- Year 1: $2.4-3,200,000 (Includes up to 3-4 Cystic Fibrosis Centers)
- Year 2: $3.4-4,500,000 (Includes up to 4-5 Cystic Fibrosis Centers)
- Year 3: $4.5-5,400,000 (Includes up to 5-6 Cystic Fibrosis Centers)

The establishment of this program would, for the first time, place the special resources for Cystic Fibrosis research at one focal point. This program, which would be unique to the NIH, supports the ongoing efforts of the NIH to eliminate the fragmentation of disease-specific resources that are currently based in more than one Institute. By consolidating Cystic Fibrosis related resources in one program, it will be possible to create and promote environments that are conducive to generating the critical masses of personnel, patient materials, facilities and data systems necessary to a concerted drive in Cystic Fibrosis research.

- NIH Management Plan. Research in Cystic Fibrosis is presently sponsored by several Institutes within the NIH. To enhance the effectiveness of these efforts, the NIH has established a Cystic Fibrosis Coordinating Committee. We urge that the activities of this Committee be continued and further expanded. Furthermore, we recommend that the National Institute of Arthritis, Metabolism and Digestive Diseases be delegated the primary responsibility for the Cystic Fibrosis Coordinating Committee since it sponsors the greatest amount of Cystic Fibrosis specific research, and has historically demonstrated a long term commitment to Cystic Fibrosis.

In order to foster cooperation between private and public research sponsors, exchange professional information, and attract new investigators into the Cystic Fibrosis field, close communication between private research sponsors, scientists and other professionals and the NIH Cystic Fibrosis Coordinating Committee should be maintained. Mechanisms should be developed to provide these non-Federal groups with representation, ad hoc membership or other participatory roles in the NIH Committee. Another means of encouraging this communication would be for the NIH and the Cystic Fibrosis Foundation to jointly sponsor periodic open scientific conferences on Cystic Fibrosis topics of interest to investigators, clinicians and others dealing with the disease.

Suggested funding:

- Year 1: $100-150,000
- Year 2: $100-150,000
- Year 3: $100-150,000

SUMMARY

In summary, the Cystic Fibrosis Foundation urges the Subcommittee to consider the following:

- A three year renewal period for the National Heart, Lung and Blood Institute as proposed in H.R. 10908.
- An increase in authorizations of appropriations for the National Heart, Lung and Blood Institute to the levels recommended by the NHLBI Advisory Council.
- A three year renewal period for the National Research Service Award Program as proposed in H.R. 10908.
- An increase in authorizations of appropriations for the National Research Service Award Program as proposed in H.R. 10908.
- A substantial increase in research activity to pursue the control and prevention of Cystic Fibrosis via the following mechanisms:
  - Cystic Fibrosis Resources Program
  - Cystic Fibrosis Research Enhancement Program
  - NIH Management Plan

We thank you for the opportunity to testify and would be pleased to respond to questions by the Subcommittee.

Mr. Maguire. Thank you.

I want to thank all of you for contributing these very thoughtful statements.

I have been browsing through your longer written statements while you were making your oral presentations.

Mr. Dresing, you are familiar with the problem that this committee faces from time to time when those who are rightly concerned about the specific disease needs that are obvious with respect to what works needs to be done, and ask to establish a separate category or a separate program that is specific to that disease.

If it turns out that the committee decides that it is not possible to proceed with establishing a cystic fibrosis research enhancement program specifically, or a resources program, as you have recommended, what alternatives would you advise might meet the research needs of cystic fibrosis?

Do you feel that your needs will only be met by setting up a specific unit, labeled specifically for cystic fibrosis?

Mr. Dresing. Mr. Maguire, I think that we have recognized through the study that we are in the process of completing with the NIH, that cystic fibrosis has, since the time of its existence, been kind of the disease without a home. We have not been privileged to have been within one institute at NIH, for instance, which would give us the kind of concentration and impact that we might be able to receive if we were somehow coordinated within one of the Institutes, and one of them took the lead for our research.

I think the timing is such that it really almost demands that we be given the opportunity to coordinate these efforts, and to place our research in a center such as we are talking about, the core center research programs, so that we might be starting to get some bank.

For so long our efforts have been so fragmented, both within our own community, and through the efforts of NIH that we might not necessarily increase the quality of the research, but for the first time be able to coordinate it so that it would have some impact.

I think that the thing that we need to look at is that on the other side of the coin, if we don't do this, the tremendous cost factor of the maintenance of the population is going to continue to grow. It is projected that by 1985, it will be between $300 and $800 million.

If we are able to, at this point, make some adjustments, and it does require some additional funding up front, but what is the payoff down the road for that kind of commitment.

Mr. Maguire. I note that on page 10 of your written statement you say that you support the ongoing efforts of the NIH to eliminate the fragmentation of disease specific resources that are currently based in more than one Institute. What does that mean?

Does it mean that you want to collect all the cystic fibrosis related research and activity into one place and all the research activity related to these other diseases in one place?

Mr. Dresing. It means that we would like to be able to have a central stop that would be the coordinating factor for the assimilation of all the information that we are gathering, and to be able to relate that specifically to our resource program that would be support in NIH.

We really don't have that now. We are really very fragmented. It is a difficult situation to work with. We would like to be able to take full advantage of the research that is being carried out on our behalf, and coordinate it so that we would be able to get a more substantial result from the efforts.

Dr. BARBERO. If I might add to that. The third part of the enhancement and resource program is that in the NIH management plan, we have worked closely with NIH in thinking this through, and see the private foundation working very closely with their mission.

I think that it has been a most imaginative approach that the Heart, Lung, and Blood Institute has done, and is anxious to do. Also, the arthritis metabolism, and other digestive diseases another institute which carries at least the most intensive part of the research effort in cystic fibrosis.

What we see is, hopefully, a cooperative venture where there will be a kind of management plan that may allow some attempt to bridge between the private foundation's efforts the NIH efforts, the cross-institution efforts in a meaningful attack.

Now we have a number of areas that are very key and perhaps that can be carried off in a cooperative way.

Mr. MAGUIRE. Mr. Dresing, you talk about controlling and preventing CF. You talk about research that you feel, basic and clinical research, that you feel might be undertaken. Can you envisage what kind of research achievements could be anticipated in the promising tracks that are now opening up; if so, what are they?

Mr. DRESING. I don't wish to preempt our report to Congress, which is not completed at this point. But I should yield to Dr. Barbero for the answer to that question, since he is our scientific man.

I feel that there are some significant factors that we have discovered through this report that indicate that there are areas of concentration that we most assuredly should be addressing ourselves to, and the promise of return is certainly there.

I would certainly not for a minute suggest that we are at the point of a break through. I don't think that this is something that we could really say in all honesty. But I think that the opportunity for us to make some definite strides in this disease are probably better than they have ever been in the past, and this is as a result of this NIH study.

Mr. MAGUIRE. Doctor, do you have an additional comments?

Dr. BARBERO. Obviously, one approach to a genetic disease is to be able to help people make informed decisions as to pregnancies. Clearly the identification of the carrier is one of the key preventive approaches.

What we are hoping is that somehow the technology that is now available will be used for looking at this kind of question. I think we do have that capability. We have a number of factors which highlight that point, and I think that their replication is very now in process.

Mr. MAGUIRE. Dr. Barclay, I was interested to note your emphasis on environmental occupational hazards, two of the issues that we have been discussing here in the last couple of days, usually in the context of discussion of cancer, but clearly applicable as well to pulmonary disease and heart disease.

It is the question of, first of all, whether it might be useful for us to have some sort of a national register of when, where and why, and from what we will die, so we can collect better data. The other would be, where there are high risk populations as a result of specific occupational or environmental exposures, perhaps we should have a way of screening those people, so that help can be brought to them as quickly as possible.

Do you have any comment on either of those suggestions?

Dr. BARCLAY. Yes, Mr. Maguire. First let me say that the American Lung Association is concerned not with a disease, but with problems afflicting the vital organ system of the body, and we have a very deep concern about cancer of the lung, which has become the number one cancer in the United States, rising in women to a level almost equal, and in some areas exceeding that of man.

We recognize the work of the American Cancer Society, but we are also interested in cancer. The lung, of course, as well as the skin, is the organ system most exposed to the environment. With our technological society, the very vital organ, the lung, for which we really have no way of substituting—for example, we do heart surgery, and we do treat heart failure, but we can do kidney transplants and dialysis for renal failure, but yet once the lung is damaged there is no way of correcting it, or compensating for it to any significant degree. So emphasis has to be placed on prevention.

You are perfectly correct in suggesting that we need better epidemiological studies for the Nation as a whole. We have to be able to identify both high risk groups and high risk areas, and high risk

We know, for example, that those who work with asbestos have

occupations.

an incidence of cancer of the lung. We know that if you are a welder, and you smoke, the incidence of cancer of the lung is extremely high. We know that if you are a farmer, you get certain fibrosing lung diseases.

We know that if you are exposed to certain fumes of nitrate that you develop a crippling fibrosis of the lung that makes you an economic burden on the health care system for a long time.

Don't interpret adversely what I am going to say. But in a sense, the patient who is killed quickly by exposure to a disease is much less a burden on society than the patient who is severly damaged and lives a very long life in a very compromised situation.

I think that cystic fibrosis and other lung diseases are a major problem to our society today, to maintain these people in some reasonable sort of life at a low economic cost. We just cannot do it.

Our medical care system is being overburdened by chronic illness where people live for many, many years and require not only expensive medical treatment, but expensive social services.

The American Lung Association and its affiliates are conducting programs to identify lung-risks in various industries. We are in cooperation with the industries, screening workers year-after-year in the hope that we will be able to identify certain high risk areas in which workers have their lungs damaged, so imperceptibly that awareness of it isn't acute.

This is another problem with lung disease. With many diseases, you identify a cause immediately. It hits you, the impacts are hard. The trouble with lung disease is that it may take 20 years of exposure in order to show, and by that time so many millions of workers have been affected that even if you interject some preventive system, you are already left with a vast population that is going to get ill as they grow older.

So I think it is absolutely crucial that we know more about the effects of the environment on lung disease.

Mr. MAGUIRE. Would you favor a national register?

Dr. BARCLAY. Yes, I would.

Mr. MAGUIRE. What about you, gentlemen, do you have a comment on the matter of registering? It is not entirely germane to your concern because it is, I take it, relatively easy to identify a person who has the disease, but not the person who may get it. You made the point that the register would not help with that.

Dr. BARBERO. I think that a registry would help because one could backtrack or go sideways around individuals, even diagnostic tools are beginning to shift. In having lived with this disease for over two-and-a-half decades, the thing that strikes me is that we are changing in our definition as a result.

A registry would show some of the changed kinds of patterns that are present.

Mr. MAGUIRE. Mr. Walgren, do you have questions?

Mr. WALGREN. No, thank you.

Mr. MAGUIRE. Thank you very much, and we appreciate your testimony.

The next panel is Dr. William Kelley, professor and chairman, Department of Medicine, University of Michigan, on behalf of the Association of American Medical Colleges, and Mr. James Jackson, on behalf of the American Psychological Association; and Constance Holleran, deputy executive director of government relations, American Nurses Association.

Dr. Kelley, would you begin?

STATEMENTS OF WILLIAM KELLEY, M.D., ON BEHALF OF ASSOCIATION OF AMERICAN MEDICAL COLLEGES AND AMERICAN FEDERATION FOR CLINICAL RESEARCH, ACCOMPANIED BY THOMAS E. MORGAN, M.D., DIRECTOR, DIVISION OF BIOMEDICAL RESEARCH (AAMC); JAMES S. JACKSON, PH. D., ON BEHALF OF AMERICAN PSYCHOLOGICAL ASSOCIATION AND ASSOCIATION FOR THE ADVANCEMENT OF PSYCHOLOGY, ACCOMPANIED BY CLARENCE J. MARTIN, EXECUTIVE DIRECTOR AND GENERAL COUNSEL (AAP); AND CONSTANCE HOLLERAN, DEPUTY EXECUTIVE DIRECTOR, GOVERNMENT RELATIONS, AMERICAN NURSES' ASSOCIATION

Dr. KELLEY. I am William Kelley, M.D., professor and chairman of the Department of Internal Medicine at the University of Michigan School of Medicine in Ann Arbor. I am a member of the American Federation for Clinical Research, the Association of Professors of Medicine and the American College of Physicians.

I am testifying before you today on behalf of the Association of American Medical Colleges and the American Federation for Clinical Research. I am accompanied by Thomas E. Morgan, M.D., director of the Division of Biomedical Research at the AAMC.

I wish to state at the outset of my remarks that the Association of American Medical Colleges and the American Federation for Clinical Research greatly appreciate the efforts that this subcommittee has undertaken in the past, and which it continues to make with this legislation, in support of biomedical research and research training.

The actions taken by you have been a central reason for the success of these programs in advancing the fight against disease and in training young scientists to continue that fight.

In the brief time allotted to me this morning, I would like to confine my remarks to the subject of research training and the renewal of the authority for the national research service awards program.

The Association of American Medical Colleges and the American Federation for Clinical Research support the provisions of H.R. 10908 with respect to the renewal of the national research service awards program and especially for 3 years because those organizations firmly believe that a strong, stable program of research training is absolutely essential to produce the numbers of skilled biomedical scientists needed to carry out the Nation's future agenda for research in the biomedical sciences.

Without these programs to attract to the biomedical and behavioral sciences a reasonable fraction of the Nation's most creative young people each year, our future scientific efforts and advances will be seriously thwarted. In particular, we support this subcommittee's intention to renew the authority for the NRSA program for 3 years, which will provide for the stability of a program which has been increasingly troubled in the past by inconstancy of Federal purpose.

The AAMC and the AFCR are in agreement with title IV, section 406 of H.R. 10908, which amends section 472(d) of the PHS Act to provide that at least 50 percent of the training awards shall be made as institutional awards and 15 percent as direct fellowships.

The Congress, through this subcommittee, has in the past emphasized the need to continue the institutional training grant program in the reports accompanying previous NRSA legislation. Despite this congressional support, the administration has tried to discontinue the institutional training grants and to award only direct individual fellowship awards.

In the justification accompanying President Carter's fiscal year 1979 budget, the Department request proposes that no new institutional awards be made in 1979 with a view to phasing out the program down to individual awards only.

It is always extremely regrettable whenever explicit inflexible program directives must be included in legislation, such as that contained in H.R. 10908 requiring specific percentages of training and fellowship awards. However, in order to prevent the administration from completely terminating institutional training awards, this language is now required.

The two organizations also endorse the language in H.R. 10908 that will extend for longer periods the time in which an individual may be supported under a National Research Service Award. This extension in time is necessary because programs leading to an M.D.-Ph. D. degree require at least 5 years and because the average length of the Ph. D. training is now more than 4 years. In addition. Ph. D.'s frequently require postdoctoral fellowship support for special purposes.

There are some additional changes which we recommend be made in the NRSA program to make this program more workable and to assure that the mission of training excellent scientists is accomplished.

National Advisory Council approval is now required by section 472(b)(2) for all National Research Service Awards, both institutional training grants and direct individual fellowship awards. Prior to 1974 both training grants and individual awards were reviewed by initial review panels, but council approval for individual awards adds to the council workload, contributes little to the review process and delays the award process by 3 to 4 months.

This delay is so long and so significant that in 1977 the clinical institutes had a large number of awards turned back by would-be physician trainees who turned to other pursuits or to other granting agencies during the 8 to 10 month wait for notification. Thus we recommend that the requirement for Advisory Council approval of individual awards be deleted.

It is not intended that peer review of awards should be discontinued, but instead that the process be shortened by returning to the pre-1974 status which required two-step review only for institutional training grants and for which no criticism has ever been developed.

We also request that the subcommittee include, in the report which will accompany H.R. 10908, a section that permits support during the acquisition of those clinical skills directly related to clinical research by those supported by National Research Service Awards.

This request is made because the training for clinical investigation requires that an individual be a superb physician as well as a superb investigator. A problem currently exists where differing interpretations of the regulations implementing the NRSA program by National Institutes of Health program managers have led to the widespread impression that no clinical work by an NRSA recipient is deemed supportable.

The AAMC supported the payback provision in the original act of 1974. Since the act became effective, we have identified certain problems. This provision poses relatively few difficulties for Ph. D.'s receiving research training especially because this subcommittee is now correcting certain inequities.

However, for research training generally and for physician research trainees in particular, we believe the payback provision is exerting a detrimental influence. The basis for this assertion is a recent survey of clinical research training in academic medical centers conducted by the AAMC for the National Research Council.

The AAMC and the AFCR recognize that in the past some individuals who received Federal research training support have gone directly into clinical practice. We support efforts to eliminate this situation, but we are more concerned that existing payback requirements discourage young physicians from entering academic careers and pose an additional barrier to individuals whose ability to perform research is untried.

It must be recognized that both M.D. and Ph. D. research trainees are performing valuable research during the training period. They more than compensate the Government for the relatively small support which they receive by publishing actively and advancing knowledge as they are being trained.

Further, the fact that it is difficult to predict in advance who will succeed in research suggests that more researchers need to enter training than will be needed, particularly in the clinical sciences. To require those who have no talent for research to remain in research careers through imposition of payback requirements is truly counterproductive and a waste of money.

We know that you are aware of the 1977 Report of the National Academy of Sciences Committee on a Study of National Needs for Biomedical and Behavioral Research Personnel. This report showed an alarming decrease in the number of M.D.'s receiving research training with Federal support, indicating that in fiscal year 1976 approximately 1,000 fewer physicians were in such research training than were recommended to meet the projected needs of this country.

We are very much afraid that unless some steps are taken to counter the detrimental effects of the payback provision, the decline in numbers of physician-investigators undertaking research with Federal research funds noted over the past few years will accelerate, at a time when more, not fewer, clinician-scientists are urgently needed.

As an alternative to payback we urge that other methods be adopted to assure that trainees are truly motivated for research careers. We suggest that an alternative approach should be adopted to assure that the objective of training for careers in research and academic medicine is attained.

The training institutions, the program directors, and prospective trainees should share the responsibility that the process of trainee selection and the nature of the training program serve only that objective.

Furthermore, the NIH should closely supervise such training programs to prevent funding of nonproductive programs and to terminate those that fail to place a majority of those completing the training program in academic/research careers. We would be glad to expand upon this proposal if desired.

Thank you very much for permitting me to appear today on behalf of the AAMC and the American Federation of Clinical Research. I would be pleased to answer any questions you may have at this time.

I would also like to emphasize that the AAMC and the AFCR support the provisions of H.R. 10908 that renew for 3 years the authorities for the programs of the National Heart, Lung and Blood Institute and the programs of the National Cancer Institute. In particular we support section 303 of H.R. 10908, which would grant to the Secretary of the Department of Health, Education, and Welfare, rather than to the President, the authority to appoint members of the National Cancer Advisory Board and to designate its chairman. Section 471 of the Public Health Service Act is also amended by H.R. 10908. We interpret this amendment to mean that Presidential appointment only of the Director of the National Institutes of Health will be required and that Presidential appointment of the Director of the National Cancer Institute will be deleted from the law. The AAMC and the AFCR support this change.

We also support the 3-year renewal provided in H.R. 10908 of the authority for the assistance to medical libraries program. Although good libraries have always been an important feature of great academic institutions, the unusual nature and array of activities subsumed by the typical academic medical center makes the quality of the services provided by its medical library of even greater than usual importance. Unfortunately, without the availability of the relatively small amounts of funds provided through the various programs of the Medical Library Assistance Act, the enhancement of those services to keep pace with both the growing magnitude and the increased complexity of activities in those centers probably would not have occurred. Unfortunately libraries are too frequently placed in a poor priority position among the many important functions of those institutions in the allocation of their always limited resources. The AAMC and the AFCR have also been impressed by the growing efficiency and effectiveness of the Regional Medical Library Network as well as the contributions which are being made through the NLM's small but very contributive research grant program.

Thank you very much for permitting me to appear today on behalf of the AAMC and the AFCR. I would be pleased at this point to respond to any questions you may have.

Mr. MAGUIRE. We will wait on questions until the panel has finished testifying.

Dr. Jackson?

STATEMENT OF JAMES S. JACKSON, PH. D.

Dr. JACKSON. Mr. Chairman, members of the subcommittee. I am very pleased to be here today to speak on behalf of the American Psychological Association and the Association for the Advancement of Psychology in support of title IV of the biomedical research and research training amendments of 1978.

My name is James Jackson. I am especially pleased to appear before this committee as a previous recipient of an award under the Public Health Service Act in 1970. I am presently an associate professor of psychology at the University of Michigan. I work in the Institute for Social Research and the Institute of Gerontology, where my research is in the factors affecting the mental health of the black population, especially the black elderly.

I administer the institutional training grants in social psychology for the University of Michigan and I presently chair the NIMH Psychology Education Training Grant Review Committee. In addition, I am chairman of the board of trustees of the Association for the Advancement of Psychology.

I am accompanied here today by Clarence J. Martin, executive director and general counsel for the Association for the Advancement of Psychology.

I would like to summarize the comments which you have before you, in terms of the record, very quickly, and then perhaps to comment on my personal experiences with regard to this particular act [see p. 395].

The revisions and extension of section 472 of the Public Health Service Act are extremely important to every scientist concerned with behavioral and biomedical research training, even more so now that section 301 training will be almost completely phased out and we will be fully reliant on the National Research Service Awards Act.

We appreciate and support your amendments authorizing increased funding for NRSA's to be awarded in the next 3 fiscal years.

We support the 3-year extension of the NRSA authority as being essential to the program's ability and continued growth, particularly in view of the equivocal history of the program for the past several years.

We support your revisions of the payback obligations. We support your cost-of-living adjustments in the stipends and allowances to NRSA recipients.

We support the increase of the maximum period of NRSA support for individuals in predoctoral training from 3 years to 5 years.

We certainly support the amendments to section 406(d) which places a floor of 50 percent on institutional grants under subsection (a)(1)(B) of NRSA.

We would like, Mr. Chairman, to suggest several changes in the legislation. We would like to clarify the intent of the Congress on the separation of the mutual exclusion of research and clinical components in training programs, to the point of excluding the application of research to clinical programs or applied environments in research programs. I will come back and speak to that a little later.

We would like to recommend a specific authority to allow support of short-term research training programs now not part of the normal academic research training system.

We would recommend provision for payback of NSRA support through appropriate activities in the nonacademic sector as well as in the academic sector.

We suggest two changes in the participation of the National Academy of Science in the NRSA. The purview of their report should be expanded to include nonacademic environments for research personnel, and the Administrator of ADAMHA should be included along with the Director of NIH as a mandatory source of consultation on the report.

Finally, we need to construct special programs aimed at identifying promising minority researchers, promoting their entrance into research, and providing special funding for programs of enrichment of their career potential.

In terms of my experiences regarding NRSA and the various roles in which I have into contact with the particular issues surrounding research in psychology, it has become known to me that most trainors of research psychologists feel the need for at least 5 years to train.

In the last 4 years, in my role on the Psychology Education Committee, I have come into contact, either personally or through various grant proposals, with almost every record around the country; each one of them have complained about the restrictions with regard to NRSA's 2 years of support.

The 5 years will be very, very helpful, and it would be very, very welcomed in the field of research psychology. There is a need for institutional awards, and we are very pleased with the changes in this bill.

The only problem with individual awards is that it does not allow the institutions to have enough flexibility with regard to making appointments. When we make appointments for psychology researchers, they come from a variety of different resources. The institution has a great deal more flexibility, and has some control over the resources for students.

Almost all of the institutions I have been to have agreed that the institutional awards would be more helpful for them than the individual awards at the predoctoral level.

The cost of living increases are important. I work with students myself at the university of Michigan, and several other universities, the awards are just inadequate with regard to inflation and other sources of increases, increases in tuition and so on. We have had to cut back with regard to our funding, and it makes it very difficult with the students.

There is a problem with regard to the separation of clinical and research training. This is a particular problem with regard to psychology. As scientists in the professional field, we often have clinical people who are trained with regard to research, although at the predoctoral level. The split between these two makes a particular hardship with regard to psychology, as I have indicated in the remainder of the testimony. Some people would like to see some real definition between these two things.

We feel that it is not the intention of Congress to make such an explicit split between research and training, but it has been interpreted this way. We would like, perhaps, some clarification with regard to that particular problem.

We have particular problems with regard to the way we turn out students. For example, I have students who chose psychology, but who are also trained in clinical psychology. It is particularly important that we be able to support people like this as they go out into the field.

Psychology as a profession creates new scientific knowledge, and it is also an applied field. We think that it is important that some connection be made between the two particular things.

We think there is a need for the alteration of the payback. As I said before, we, indeed, do support the payback provision, but we do believe that there needs to be some alterations made. What has happened in psychology in the last few years, we move more and more out of the academic realm because of the need for psychological researchers and industry, and in business and other kinds of fields.

We would like to see an alteration made so that people can take care of the payback provision by, perhaps, working in research in other than academic institutions. We think that this is a simple change to be made.

Also we think that it is important that conference be exempt from payback provisions. The way that the bill reads right now, if we have a conference, the people who participated in the conference would be supported, but the students would not exempt from the payback provision.

It is very important, and in the last 4 years we have supported several medical conferences, which have been important with regard to increasing minority students.

Finally, I think that there is a need for special programs with regard to minority students. I think we need the kind of program that is available at NIH. I think that it would be very, very helpful to have such a program at NIMH with regard to increasing the number of minority students who are involved in psychology training.

Thank you.

[Testimony resumes on p. 404.]

[Dr. Jackson's prepared statement follows:]

Testimony of

James S. Jackson, Ph.D.
University of Michigan

Accompanied by

Clarence J. Martin
Executive Director and General Counsel
Association for the Advancement of Psychology
Washington, D. C.

on behalf of the

AMERICAN PSYCHOLOGICAL ASSOCIATION
&
ASSOCIATION FOR THE ADVANCEMENT OF PSYCHOLOGY

Before the

Subcommittee on Health and Environment
Committee on Interstate and Foreign Commerce
U.S. House of Representatives

March 3, 1978

on the subject of

H.R. 1098

Biomedical Research and Research Training

402

SUBCOMMITTEE ON HEALTH AND ENVIRONMENT
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE
U.S. HOUSE OF REPRESENTATIVES
H.R.1098

Mr. Chairman, members of the Subcommittee on Health and Environment.

I am very pleased to be here today to speak on behalf of the American Psychological Association and the Association for the Advancement of Psychology in support of Title IV of the Biomedical Research and Research Training Amendments of 1978.

My name is James Jackson. I am especially pleased to appear before this Committee as a recipient of an award under the Public Health Service Act in 1970. I am presently an Associate Professor of Psychology at the University of Michigan. I work in the Institute for Social Research and the Institute of Gerontology, where my research is in the factors affecting the mental health of the black population, especially the black elderly. I administer the institutional training grants in social psychology for the University of Michigan and I presently Chair the NIMH Psychology Education Training Grant Review Committee. In addition, I am Chairman of the Board of Trustees of the Association for the Advancement of Psychology.

I am accompanied here today by Clarence J. Martin, Executive Director and General Counsel for the Association for the Advancement of Psychology.

The revisions and extension of Section 472 of the Public Health Service Act are extremely important to every scientist concerned with behavioral or biomedical research training -- even more so now that Section 301 training will be almost completely phased out and we will be fully reliant on the National Research Service Awards Act.

We appreciate and support your amendments authorizing increased funding for NRSA's to be awarded in the next three fiscal years.

We support the three year extension of the NRSA authority as being essential to the program's stability and continued growth, particularly in view of the equivocal history of the program for the past several years.

We support your revisions of the pay-back obligations. We support your cost-of-living adjustments in stipends and allowances to NRSA recipients.

We support the increase of the maximum period of NRSA support for individuals in pre-doctoral training from three years to five years.

And we certainly support the amendments to Section 406(d) which places a floor of 50 per centum on institutional grants under Subsection (a)(1)(B) of NRSA.

We would, Mr. Chairman, like to suggest several changes in the legislation.

We would like to clairfy the intent of the Congress on the separation of programs funded under Sections 472 and 303. The Executive Branch has been strict in the mutual exclusion of research and clinical components in training programs: to the point of excluding the application of research to clinical programs or applied environments in research programs.

We would like to recommend a specific authority to allow support of short term research training programs not now part of the normal academic research training system.

We would recommend provision for pay-back of NRSA support through appropriate activities in the non-academic sector as well as the academic.

We suggest two changes in the participation of the National Academy of Science in the NRSA. The purview of their report should be expanded to include non-academic environments for research personel, and the Administrator of ADAMHA should be included along with the Director of NIH as a mandatory source of consultation on the report.

Finally, we need to construct special programs aimed at identifying promising minority researchers, promoting their entrance into research, and providing special funding for programs of enrichment of their career potential.

Let me comment in further detail.

The increase in the maximum period of support under the NRSA program to five years of predoctoral support plus three years of postdoctoral support is a very welcome addition. The flexibility that this modification creates will be directly beneficial to students who are in their first years of predoctoral training, and are not yet qualified to perform teaching duties. This group of students have often been left out of funding programs, and consequently were at a serious financial disadvantage. Particularly hard hit have been women and minority students, who often are not able to pay their own way through school, and who are forced to take part-time jobs outside the academic environment. Often these students are not able to be full-time students because of their financial problems. This part-time status increases the time required to complete their degree, lessens the feeling of commitment to the educational and research enterprise, and tends to be a major factor in the number of drop-outs from training programs.

The new five-year limitation for predoctoral support will be of particular advantage for students in those disciplines such as psychology, that have put their emphasis on research training at the predoctoral level rather than the postdoctoral level. Since many of the provisions of the original National Research Service Awards program were written with physicians in mind, they have not worked to the advantage of the non-medical research professions. In addition, a certain inflexibility in administration of the NRSA legislation has led to further serious consequences for research training in these behavioral, rather than biomedical sciences. Your modification of the maximum period of support under NRSA will be very advantageous to those students who are in real financial need.

The stability of research funding to institutions of higher learning is of the utmost importance if we are to have a consistent production of good research and well trained research personnel. The requirement in the Amendments that at least 50 percent of the NRSA funds shall go to institutional awards is a very positive step in promoting that stability of research funding. This requirement will allow the universities to make use of their talented staff and student populations to their best mutual advantage. It will allow the school the flexibility to allocate funds among research trainees based upon individual financial need as well as potential for excellence in a research career. This should also, we feel, reduce the administrative costs necessarily associated with a financial aid program of this magnitude. Our university programs need visible and continuing support from our government, particularly in their efforts to develop and disseminate new knowledge. This action by the Subcommittee will be another helpful step toward stability and the appropriate allocation of resources to the university system.

The provision in the Amendments which adds cost-of-living increases to the stipends awarded under NRSA is an extremely welcome change. For the past years, the amount of the NRSA awards has stayed at a fixed level. With rises in tuition, and particularly with the dramatic increase in the cost of living, students supported with NRSA funds were being caught in a financial bind. In addition, the recent decision by the Internal Revenue Service that makes the NRSA stipends taxable income has created an onerous burden on the students. While we realize that a modification of the tax status of the Awards is not within the purview of this Subcommittee, we join other groups in urging your support for corrective legislation to change this tax status -- as was recently done for the National Health Service Corps Scholarship Program. The addition of the cost-of-living allowances to the stipend, however, is a major step in recognizing the plight of many students who rely on NRSA funds for their entire support.

In addition to these changes in NRSA proposed by the Amendments, we would like to suggest others which we feel will be of assistance in the training of research personnel.

First: The provision in the original legislation that disallowed NRSA support for clinical training has been interpreted by the Executive Branch in a somewhat limited fashion. To quote from Page 10 of the Report on the House Bill, "National Biomedical Research Fellowship, Traineeship, and Training Act of 1973, "...in writing this legislation the Committee has felt if appropriate to restrict its application to actual research training. This should not be interpreted to mean that the present NIMH support for clinical and practice training is inappropriate. Rather, it is an appropriate subject for separate consideration from that of research training." We heartily agree that both clinical and research training are important, but are concerned that the separation of the two aspects of training has been made too completely by the Executive Branch.

As we understand it, NIMH has interpreted the congressional separation of clinical and research training to be absolute. Hence, in a program that proposes to combine some clinical skills within research training -- NIMH requires that two applications be submitted, as though these were separate programs. On the surface, this is only a cumbersome procedure, not a problemmatic one. However, for psychology it causes particular problems.

Psychologists represent 11 percent of all doctoral-level scientists produced in the country and a much larger percentage of the behavioral science doctorates. Also, psychologists represent over 50 percent of the doctoral-level mental health service providers in the country. The education for a clinical psychologist has always included a significant amount of training in research methods, and the surveys of clinical psychologists over the years have shown that a significant amount of professional time is spent in research activities. This duality of research and practice does not fit with the separate NIMH administrative categories of support. This duality is, however, at the very essence of psychological training.

We would very much appreciate the Subcommittee's help in clarifying the intent of Congress that clinical training and research training need not be totally separate to be appropriate for support through federal funds. We would like some acknowledgement that, for the discipline of psychology at least, there is a necessity for research training within the clinical program; and, that for all disciplines there is a necessity for environments that promote the application of research to clinical problems.

Second: We recommend the NRSA authority be modified to allow support of short-term research training programs, without the requirement for service payback. Presently there is no mechanism for the government to provide financial support to summer workshops, conferences, or intensive, but brief training programs that are not part of the normal academic research training system. An amendment to the NRSA legislation that specifically allows such funding would be of great benefit as a catalyst toward greater sharing of research interests and findings, new methods of research investigation, and promising new avenues of research effort. While many such programs are not expensive relative to their usefulness, they often require outside funding if they are to be possible within the academic community. The ability to gather promising new researchers and highly respected experts for their expansion and cross-fertilization of ideas would be significantly increased with funding possibilities from the National Research Service Award legislation.

Third: The provisions for payback of NRSA support through research services is presently listed as follows: (the awardee shall) "engage in health research or teaching or any combination thereof which is in accordance with usual patterns of academic employment." We recommend that the Subcommittee consider expanding that preferred method of payback to include appropriate research activities in the non-academic sector.

For psychologists, particularly, and for other behavioral scientists also, there is a trend to seek employment outside of the universities. This trend has been in response to the need expressed for behavioral science knowledge by government agencies, research organizations, the military services, industrial and management groups, and private businesses. The creation of a massive network of state and local health planning agencies has led to an unfulfilled demand for qualified researchers. The requirements of Congress for appropriate data and studies from the Executive Branch has led to increased use of federal funds to support the collection and interpretation of that information. The National Academy of Sciences is required to perform an intensive and extensive study of the needs for research personnel -- to thereby provide a basis for policy making in research training priorities.

All of these examples are outside the usual patterns of academic employment, yet are clearly very beneficial to the public and its government. It seems appropriate, therefore, to recognize the need for research personnel outside the universities by including in these Amendments a provision that also allows payback through work in "health research or health services research in a governmental or non-profit non-governmental agency or organization."

Fourth: The National Academy of Sciences study on personnel needs for biomedical and behavioral research personnel is modified by two sections in these Amendments. Section 402 makes the study an advisory input to the Secretary of Health, Education and Welfare, rather than a document at the core of research training policy. Section 407 decreases the frequency of the reports to once every three years, rather than once each year.

We would like to argue against these changes in the study and its influence.

Although organized psychology has not always agreed with the particular recommendations of the studies, we have watched and participated in its improvement over the past years. We would like to see the efforts of this Subcommittee work toward advancement of the quality of the report rather than work toward diminution of its impact. The authorization of a scientific study to be used as the basic input for public policy was a very progressive action by Congress. Since one of the purposes of authorizing the study was to promote stability and long-range planning in research training policy, we do not think that support for planning and stability should be withdrawn in any way.

The change in frequency of reports from the National Academy of Sciences to once every three years does not seem compatible with the need for current data and recommendations on the national requirement for research personnel. The time lag between the initial call for training in any research specialty and the production of these research personnel is long enough as it is. The reports produced thus far have been based on a combination of continuing surveys of need plus new surveys to determine research personnel need in emerging areas. The response time required to influence training priorities would be tripled if this section of the Amendments were passed.

We would like to suggest, however, two changes in the legislation authorizing the National Academy of Sciences report.

First: As suggested earlier in our testimony, the need and the utilization of research personnel in non-academic environments has increased over the past few years -- and will likely increase at a more rapid pace in the future. The 1977 report suggested that there are plans to examine this non-academic research potential more fully in 1978. However, as the present payback provisions include only the academic sector, this look into non-academic settings for research may not receive the emphasis that it needs.

We ask that the Subcommittee modify the stated purpose of the report so that the study would identify "the Nation's overall need for biomedical and behavioral research personnel in academic and non-academic research and training environments." This change would not only be a recognition of the usefulness of such information, but would also be a supportive statement for the stated plans of the National Academy of Sciences.

Second: A technical change in the last sentence of Section 473 which authorizes the study and report would seem helpful. At present, the National Academy of Sciences is required to conduct the study of research personnel needs "in consultation with the Director of the National Institutes of Health." We suggest that, in recognition of the other major source of NRSA funds, the study also be made "in consultation with the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration." While consultation with ADAMHA is certainly going on now, it seems reasonable to make this technical change to recognize the appropriateness of this cooperation.

Finally, there is a need to recognize the particular problems of recruiting and retaining minority students for research careers. As we mentioned earlier, the change in the maximum number of years of support made by these Amendments would be very helpful to minority students. Providing for the possibility of support for five years of pre-doctoral training will be directly beneficial. Also, the inclusion of cost-of-living increases for stipend support will enable more minority students to receive their research training without the interference of part-time work.

There is, however, a need to plan and carry out special programs aimed at identifying promising minority researchers, promoting their entrance into research careers, and providing special funding for programs of enrichment of their career potential.

A program of such support is now in progress at the National Institutes of Health. We would like the Subcommittee's support for this type of program within the Alcohol, Drug Abuse, and Mental Health Administration.

A program that works to identify potential behavioral scientists among minority high school students, and promotes their scientific development through graduate study would be of dramatic benefit to the present attempts at increasing the number of minority researchers. The programs of the National Science Foundation to bring high school students into science careers, for example, has been credited by a number of persons as a very important factor in their later career choice of a science discipline.

We feel that the recommendations of the National Academy of Sciences regarding the need for minority researchers are inadequate. While they suggest the creation of post-doctoral training programs to recruit minority scientists into research careers, we urge that such programs be created to guide and support the identification, development and education of minority students long before their careers have been chosen. We hope you can support our recommendations.

I appreciate this opportunity to appear before this Subcommittee and submit our testimony for consideration. We very much appreciate the effort you have made to improve the National Research Service Awards program, and hope you will consider our suggestions and requests.

Thank you very much.

Mr. MAGUIRE. Thank you, Mr. Jackson.
Ms. Holleran?

STATEMENT OF CONSTANCE HOLLERAN

Ms. HOLLERAN. Thank you, Mr. Chairman. We are pleased to have the opportunity to be here today to speak in support of H.R. 10908. My comments will focus on the National Research Service Award section of that bill [see p. 406].

We are grateful to this committee for its previous action in specifically including under the National Research Service Awards, authorization for nursing research training grants administered by the Division of Nursing, Health Resources Administration.

The nursing research training program had suffered seriously before that action was taken. However, with that authorization and the congressional appropriation of funds, the program has been revitalized. For example, it was possible to award 91 fellowships in fiscal 1977 compared to only 12 in 1976.

The interest of individual nurses and the commitment of the profession to nursing research for the improvement of nursing practice and patient care has grown tremendously in recent years. The number of nurses prepared for research related to nursing has increased from a mere handful in 1955 to more than 900 in 1972 and some 1,500 today.

In its 1977 report, the National Academy of Sciences' committee on a "Study of National Needs for Biomedical and Behavioral Research" included for the first time a discussion of the need for advanced training in the area of nursing research. The report affirms that: "Nursing research is properly regarded today as a distinct area of scientific inquiry."

Nursing research focuses on the role of nursing care in the prevention of illness, care of the ill and the promotion and restoration of health. This is distinct from biomedical research, which focuses on the science of cure.

Nurse researchers are engaged in investigations designed to identify better methods of care, such as strategies for reducing the complications and costs of hospitalization; facilitation of home-based and self-care in chronic illness; improving the outlook for high risk groups such as premature infants and the elderly; and reducing disabilities, discomforts and costs of coronary and cerebral-vascular problems.

Such research includes studies focused on alleviation of pain, care of burned patients, prevention of postsurgical infection and care of the patient using home dialysis.

In 1960 the American Nurses' Association established a list of priorities for nursing research, which included the effects of the performance of nursing activities on patient care, nursing needs of patients, and nursing in different categories of illness, such as conditions requiring surgical care. The priorities have been revised regularly.

The Academy of Sciences in its report recommends that support for predoctoral and postdoctoral nursing research training awards be increased to provide for 225 individuals in 1979, 240 in 1980 and

270 in 1981. They also advise that up to 15 percent of the funds be made available to postdoctoral applicants, and we think that it is an appropriate step at this time.

I would like to call the committee's attention to the serious problems created by the termination of the Nursing Research and Education Advisory Committee by HEW at the recommendation of OMB. We have spoken to the unique nature of nursing research, and that advisory committee is the only peer review group for nursing research in the Federal Government.

That committee is comprised of nurse scientists and nonnurse scientists knowledgeable about the field.

We support the increase in years of support proposed in section 403 and the stipend cost of living increases authorized in section 404. Both of these changes are really needed and will benefit the trainees.

In section 405, the liberalization of the payback penalty provision seems appropriate. Evidence of problems for nurse researchers to date is hard to assess due to the recency of the inclusion of nursing in the legislation and the time required to complete training. As stated earlier, nurse researchers do stay active in teaching and/or research.

In view of the successes of nursing research and its developing momentum, I would like to speak to the "Experts and Consultants" portion of H.R. 10908. The need for flexibility in attracting scientists to government for varying periods of time is real. We ask that you make this provision, section 477, applicable to the research program administered by the Division of Nursing of HRA as well.

We agree with Dr. Frederickson who testified the other day that to have a specific number identified would be helpful. We believe that up to five such appointees for nursing would be useful at this time.

We appreciate the opportunity to participate in this discussion, and we do support the bill.

[Testimony resumes on p. 413.]

[Ms. Holleran's prepared statement follows:]

AMERICAN NURSES' ASSOCIATION

Testimony on

H.R. 10908

Biomedical Research and Research Training Amendments of 1978

By

Constance Holleran

We are pleased to have the opportunity to be here today to speak to H.R. 10908. We support this legislation to extend support for the Library of Medicine, biomedical and behavioral research and the National Research Service Awards.

The Library of Medicine serves both a national and an international need. We have been concerned about the long standing vacancies on that Board of Regents and do hope that those appointments can be cleared soon. The inclusion of a nurse researcher on that Board we feel would be appropriate. We do urge continued support for the Library.

We are grateful to this committee for its previous action in specifically including under the National Research Service Awards, authorization for nursing research training awards administered by the Division of Nursing, Health Resources Administration.

The nursing research training program had suffered seriously before that action was taken. However, with that authorization and the Congressional appropriation of funds, the program has been revitalized. For example, it was possible to award 91 fellowships in fiscal 1977 compared to only 12 in 1976.

The interest of individual nurses and the committment of the profession to nursing research for the improvement of nursing practice and patient care has grown tremendously in recent years. The number of nurses prepared for research related to nursing has increased from a mere handful in 1955 to more than 900 in 1972 and some 1500 today.

This is a substantial increase, but the number is still woefully small. The total number of nurses with doctorates of any kind is only about 1800, less than one percent of all registered nurses in the country.

The growing interest of nurses in receiving such advanced preparation is reflected in the numbers of applications for nursing fellowships received by the Division of Nursing. There have been more than 230 applications since the awards became available in the fall of 1976 under the new authorization.

In its 1977 Report, the National Academy of Sciences' Committee on a Study of National Needs for Biomedical and Behavioral Research included for the first time a discussion of the need for advanced training in the area of nursing research. The Report affirms that "nursing research is properly regarded today as a distinct area of scientific inquiry."

Nursing research focuses on the role of nursing care in the prevention of illness, care of the ill and the promotion and restoration of health. This is distinct from biomedical research, which focuses on the science of cure. Nursing research is concerned with developing the science of health care - addressing the human and behavioral questions that arise in the treatment of disease and the prevention of illness and maintenance of health.

Nurse researchers are engaged in investigations designed to identify better methods of care, such as strategies for reducing the complications and costs of hospitalization; facilitation of home-based and self-care in chronic illness; improving the outlook for high risk groups such as premature infants and the elderly; and reducing disabilities, discomforts and costs of coronary and cerebral-vascular problems. Such research includes studies focused on alleviation of pain, care of burned patients, prevention of post-surgical infection and care of the patient using home dialysis.

Nursing research on care of dying patients has led to programs for home care, which have great benefits both for the patient and for his family. The January issue of McCall's magazine carried an article describing such a program of home care for children with cancer developed at the University of Minnesota. The research team (headed by a nurse and with nurses and people from other disciplines as members) estimates that 80 percent of the 3,000 children who die of cancer each year in this country could be cared for at home with the parents as the primary caretakers and the nurse teaching them how to provide needed care.

As is pointed out in the National Academy of Sciences Report, early nursing research in this country developed out of a need for the systematic assessment of the general procedures used by nurses in patient care. The federal interest in nursing practice after World War II stimulated research focusing on specific clinical skills. There were assessments on the role of the nurse in psychiatric services, maternal and child care, pediatric care and others. There was a shift away from the initial concern with professional procedures to an interest in the role of the patient in nursing care, and the patient has remained the focus.

In 1960 the American Nurses' Association established a list of priorities for nursing research, which included the effects of the performance of nursing activities on patient care, nursing needs of patients and nursing in different categories of illness, such as conditions requiring surgical care. The priorities have been revised regularly.

When nursing research turned from a concern with the organization and practice of nursing to the broader concept of nursing care of impairments that accompany health problems, such as pain and anxiety and the specific needs of patients and potential users of the health care system, the availability of federal support began to play a major role in the development of nursing research as an area of scientific inquiry.

Following are some of the areas for nursing research that have been identified in previous testimony to this committee and to the President's Panel on Biomedical Research:

1) studies to reduce complications of hospitalization and surgery
2) studies to improve the outlook for high risk parents and high risk infants
3) studies to improve the health care of the elderly
4) studies of life-threatening situations, anxiety, pain and stress
5) studies of adaptation to chronic illness and the development of self-care systems

6) studies to facilitate the successful utilization of new technological developments in patient care
7) studies of effective intervention in community mental health settings.

The ANA Commission on Nursing Research has since made some additions to these priorities:

1) studies of nursing interventions to promote health
2) studies to facilitate the successful application of new knowledge to patient care
3) studies to define and delineate health states
4) studies of addictive and adherence behaviors
5) studies of under- and over-nutrition
6) studies to evaluate the outcomes and/or effectiveness to consumers and providers of different patterns of delivery of nursing services.

The Academy of Sciences in its report recommends that support for pre-doctoral and post doctoral nursing research training awards be increased to provide for 225 individuals in 1979, 240 in 1980 and 270 in 1981. They also advise that up to 15% of the funds be made available to post doctoral applicants, and we think that is an appropriate step at this time.

Another significant point made in the Academy report is in regard to the market for nurses with doctoral degrees. A reported survey showed that employment opportunities for doctorally trained people were better for nurses than for other biomedical and behavioral scientists.

Almost 95 percent of nurse doctoral graduates held full-time positions, and all but three percent of the nurses held positions for which they considered their doctoral training relevant.

In contrast with other biomedical and behavioral scientists, doctoral nurses received more federal training support in the first two years of graduate school than in later years. Forty-one percent, however, relied on federal support in their fourth year of graduate school. Approximately 60 percent of those who received any federal support indicated that without such support they would not have been able to finish their doctoral programs.

We would like to call the committee's attention to the serious problems created by the termination of the Nursing Research and Education Advisory Committee by HEW at the recommendation of OMB. We have spoken to the unique nature of nursing research, and this advisory committee is the only peer review group for nursing research in the federal government.

Most research review panels in the federal health agencies are attuned to biomedical research related to disease. They are comprised mainly of physicians and representatives of basic biomedical sciences. We believe that nursing research must be reviewed by panels oriented to the broad aspects of health care, which is the nursing research focus.

The Health Resources Administration Nursing Research and Education Advisory Committee members have served as peer reviewers to both beginning and experienced nurse researchers by screening and evaluating research grant applications each year, as well as reviewing individual and institutional fellowship applications. At this juncture in the development of nursing research, we believe it is absolutely essential that such review continue to be done by a review committee that is thoroughly familiar with the problems and science of nursing. The current review committee is comprised of nurse scientists and other scientists familiar with the field.

With the current much needed emphasis on improvement of health care delivery, we believe it is a most ill-considered action to terminate the nursing research advisory group. We would hope that this committee will consider action to counter this most unfortunate decision on the part of the Administration.

We support the increase in years of support proposed in Sec. 403 and the stipend cost of living increases authorized in Sec. 404. Both of these changes are really needed and will benefit the trainees.

In Sec. 405 the liberalization of the pay back penalty provision seems appropriate. Evidence of problems to date is hard to assess due to the recency of the inclusion of nursing in the legislation and the time required to complete training. As stated earlier, nurse researchers do stay active in teaching and/or research.

In view of the successes of nursing research and its developing momentum, I would like to speak to the Experts and Consultants portion of H.R. 10908 The need for flexibility in attracting scientists to government for varying periods of time is real. We ask that you make this provision (Sec 477) applicable to the Research program administered by the Division of Nursing of HRA as well.

We appreciate the opportunity to participate in this hearing.

Mr. **Maguire.** Thank you.

Mr. Walgren?

Mr. **Walgren.** I wanted to ask, what arguments are there for eliminating the institutional grants and National Research Service Awards?

Mr. **Martin.** I have never heard a good one, to tell you the truth, Mr. Walgren.

Mr. **Walgren.** Is there nothing to be said about that at all?

Mr. **Maguire.** If you would identify yourself, sir, for the record?

Mr. **Martin.** I am Clarence Martin, and I am general counsel of the Association for the Advancement of Psychology.

There is, and some of this is historical. It goes back to the revisions made originally by the Nixon administration—the first Nixon administration—in which there was a very strong concern to target all science toward very narrow series of programs.

It was felt at that time that by controlling it in HEW bureaucracy, they could select exactly where the training went. When you put it in the institutions there was more likelihood that the money would go wherever the flow of science took it, rather than where the targeted that were chosen by the Federal Government.

I think that it is more of a management issue within the Federal Government than it is anything else. It is sort of being clung to for that purpose. That is the only reason I know. There may be others, but that is the way that it appears to me.

Dr. **Jackson.** The issue is problematic. It is more costly to administer program of this nature with individual grants, because each one has to be administered in some way, both at the Federal level and at the level of the local institution.

I think that Clarence is perfectly correct in his assessment of how that came about. There was also the feeling that, somehow, these grants were providing some support for the institutions. It is not true. There is not a great deal of money provided for the institution. I think that the argument is much stronger for institutional programs than it is against institutional programs, if you want my opinion.

Dr. **Kelley.** I would support exactly what has been said. I think, clearly, one could make substantial argument for the institutional support.

I think that one other conceivable component may well have been that institutional grants, of course, generally go to the strongest programs. There may have been individuals in weaker programs who felt that they were not appropriately competitive for potential trainees. I would wonder if that might not also have been a factor.

Dr. **Morgan.** It is a little hard to decide what the Office of Management and Budget has in mind, since they are not typically witnesses at these hearings, Mr. Walgren. But our Association has over the years noted that whatever the incumbent President's policies may be, the practices of the OMB seem to be to try to limit the pressures for research funding, controlling the cost within DHEW, and bringing the cost under control by management principles. We assume that one of these management principles would be to try to reduce the number of people being trained and, therefore, reduce the number of those who generate pressures for research grants.

If the Congress decides that the Congress wants a vigorous program of research, it must necessarily support a vigorous program of introduction of fresh minds to do that research. Therefore, it must support research training.

Mr. Walgren. Thank you, Mr. Chairman.

Mr. Maguire. Thank you.

We do have a quorum call. Each of the three groups here have taken different positions on the payback. You would like to eliminate it and replace it with I am not quite sure what, although you have offered to tell us at greater length.

Dr. Jackson, you have suggested some modifications. Let me quickly ask you if you are wanting to permit shorter term activities, conferences and seminars, and what-have-you, short-term research. What would be your time frame, would you say less than 3 months, or anything less than a year to be free of payback or what?

Dr. Jackson. Our typical conferences have taken a shorter span of time than that. We have discussed the possibility of weeklong conferences or a series of weekly conferences over a period of a couple of years.

Mr. Maguire. Other than that, you have no objection to a payback provision?

Dr. Jackson. Given the hiring patterns of people in psychology, that is not a particular problem for us in our field. Very few of our people go into private practice, less than 3 percent, as a matter of fact. But we do think that it is important, with regard to payback, that it be changed.

A lot of our people go into fields other than academic, and this causes some problems. This is one of the problems with regard to payback.

Mr. Maguire. Ms. Holleran, you are not very specific. You want more flexibility, but you have not said what?

Ms. Holleran. We have not had a lot of problem in our field yet. I was speaking of the problems of medicine because of the clinical practice issue.

Mr. Maguire. May I suggest, Dr. Kelley, that you might present to the committee a lengthier explanation of what you are interested in. As far as I can tell, you are proposing that everybody share the responsibility, and you hope that something will happen; second, if people don't perform in terms of producing people into the sector that we are talking about, they should have their funds cut off.

I would like to hear a little bit more about that, and I am sure that the committee would.

[The following information was received for the record:]

New Training Grant Awards

For new training grant awards, the payback provision shall continue for the first 2 years of the award. After the first 2 years, the project director may elect an alternate proposal—option A—as described below.

(a) The trainee would not personally be bound to the payback provision.

(b) The program director of each institutional training grant in clinical sciences choosing option A must select trainees and their training curricula very carefully and must assure that the majority of graduates of each program engage in research or teaching activities for a period at least equal to that for which Federal research training support was received under NRSA. "Research or teaching activities" are now defined in the law as "health research or teaching or any combination thereof in accordance with usual patterns of academic employment," section 472(c)(1)(A)(i).

(c) The program director of each institutional training grant choosing option A shall furnish to the NIH on July 15 of each year the name, address, and current activities—for example, research, practice, teaching—of each program graduate for the previous 5 years.

(d) The NIH shall monitor very carefully the information furnished to it to assure that each program selecting option A places at least a majority of its graduates on the average in research or teaching.

(e) If a program operating under option A fails to place the required number of trainees in research or teaching, NIH shall reduce the number of trainees supported for the remainder of the award period. The grant will not be renewed if the average number of graduates entering research or teaching for the life of the award is less than a majority.

Mr. MAGUIRE. I am going to have to terminate this panel, and I will call the next panel in 10 minutes, when I get back from the floor.

[Brief recess.]

Mr. MAGUIRE. The last panel is composed of four panelists, John A. Timour, university librarian, Thomas Jefferson University, on behalf of the American Library Association; Nina W. Matheson, director, Health Sciences Library, George Washington University Medical Center, on behalf of the Medical Library Association; Samuel Hitt, director, Health Science Library, University of North Carolina at Chapel Hill, on behalf of the Association of Academic Health Sciences Library Directors; and Alfred N. Brandon, director, the New York Academy of Medicine Library, on behalf of the New York and New Jersey Regional Medical Library.

Ms. MATHESON. Mr. Chairman, if it is all right with you, we would like to proceed in the order that we are sitting around the table.

Mr. MAGUIRE. That is fine with me.

STATEMENTS OF NINA W. MATHESON, ON BEHALF OF MEDICAL LIBRARY ASSOCIATION; SAMUEL HITT, ON BEHALF OF ASSOCIATION OF ACADEMIC HEALTH SCIENCES LIBRARY DIRECTORS; ALFRED N. BRANDON, DIRECTOR, NEW YORK AND NEW JERSEY REGIONAL MEDICAL LIBRARY; AND JOHN A. TIMOUR, ON BEHALF OF AMERICAN LIBRARY ASSOCIATION

Ms. MATHESON. My name is Nina Matheson, and I am the director of the Health Sciences Library at George Washington University Medical Center here in Washington, D.C. I am representing the Medical Library Association.

My colleagues, Mr. Brandon, Mr. Hitt, and Mr. Timour, represent other sectors within the general health sciences information community, and they will speak to those sections of the legislation with which they have concerns. My concern is with the research and resource sections of the act.

We have each submitted formal statements for the record, and in view of the short amount of time, I would like very much to divert from the testimony and summarize the main points [see p. 418].

Mr. MAGUIRE. That will be fine. We will submit, for the record, all of the written statements in their entirety.

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Ms. Matheson. You will remember that in 1965, when the Medical Library Act was first passed, Sputnik had just swept across the skies, and it reminded us of how far behind the other nations of the world we had fallen with respect to scientific research. A survey of libraries at that time also revealed that many health science libraries were physically in a dilapidation condition, the collections were inadequate to support intensified research programs in science and medicine.

Since 1965, a considerable amount has been accomplished. There have been 1,400 grants awarded to more than 600 institutions. The Regional Medical Library network was created to facilitate the transfer of documents across the country in an organized way. There are more than 2,500 health science libraries involved in that network. But this really is not very much in terms of the total overall need. There are 8,000 health libraries in this country serving more than 5 million health workers. Although we feel that there have been tremendous strides made, there is still yet a great deal more needed.

The two programs that I am most concerned with are the research and resource programs. The research program, among the five programs, is the one that needs the strongest support; that is, research in library and information processes. Over the past decade, actually only 3 percent of the $90 million allocated to this section of the program has been awarded for library-related research. I think you probably recognize that the basic and applied research questions have not been fully explored. Actually very little is understood about the most effective methods to transfer information.

Libraries need to develop tools to help them utilize their existing resources better. For example, the National Library of Medicine offers an online data base called MEDLINE. It is the online version of the printed Index Medicus. There is currently a grant at the Beth Israel Hospital in Boston, Mass., where they are exploring the possibility of stripping off portions of that data base, and put it on a minicomputer in their hospital, so that they can retrieve more effectively the hospital literature that is available. This is an example of the kind of research that we need more of.

Resource improvement grants have been very effective in stimulating local community hospital library development. Here again there are still many needs. One of the most important, I believe, is reaching the rural practitioner who is working at a community hospital that is not tied into a network. He has difficulty accessing the actual resource. He can get bibliographic information through MEDLINE, but getting the actual article in hand is the problem. Many more community hospitals need to be integrated into the regional medical library system. In view of the enormous increases in the cost of information, we need to encourage more local hospital consortium development. In 1969, the average health science journal cost $19. Today, that same journal costs $51. So there is tremendous pressure on the local hospital to share their resources so that they can expand the breadth of materials that are available.

We believe that the work under the Medical Library Assistance Act has developed a strong foundation, but we also believe that the foundation that has been built is susceptible to erosion unless we intensify the efforts to upgrade the program. The program has been consistently underfunded: 1,400 grants were made to 600 institutions, and yet there are 8,000 institutions that are really involved in this information delivery system. I am sure you recognize that it is not possible to mount a research program, or even a service program, without providing a supporting information system. Even in the Congress where mountains of material arrives every day, you have an information retrieval problem. That material is only useful if it is properly organized and if it gets to the right people who need it at the right time. For these reasons, we believe that the Medical Library Assistance Act is essential to support our national health objectives. We recommend the 5-year renewal. We believe that a 3-year extension would be the minimum needed. We would like to see dramatically increased funding levels. We believe that it is necessary, therefore, to increase the authorization levels and recommend that the amounts in H.R. 10908 be increased to those recommended in the Senate bill S. 2450. That is: $15 million in 1979; $17 million in 1980; and $21 million for 1981 to 1983.

Thank you for the opportunity to tell you about our concerns. Mr. Hitt will be the next speaker.

[Testimony resumes on p. 426.]

[Mrs. Matheson's prepared statement and attachment follow:]

TESTIMONY BY

NINA W. MATHESON, DIRECTOR
PAUL HIMMELFARB HEALTH SCIENCES LIBRARY
GEORGE WASHINGTON UNIVERSITY
WASHINGTON, D.C.

REPRESENTING

MEDICAL LIBRARY ASSOCIATION

Mr. Chairman and Members of the Committee:

The Medical Library Assistance program represents collaborative efforts between the health sciences library community and the National Library of Medicine to develop facilities and techniques for dissemination and use of health science information. This program needs increased authorization and appropriations for the following purposes: to award research grants to investigate new procedures in biomedical and health information delivery; to expand training grants to emphasize support for training health science librarians to utilize modern technologies in telecommunication, computer science and automated library technical processing systems; to support efforts to develop the health science information network to the point where community hospitals and health care institutions have immediate access to high-demand biomedical information; and to expand and improve services of the Regional Medical Library program.

IMPORTANCE OF THE ACT

There are over 5 million health workers in practice today, each type relying on health information to perform their jobs well. The nation's practicing clinicians are dependent on a rapid flow of biomedical information for the transfer of tested laboratory discoveries to the patient's bedside. Health researchers need current information so that they can conduct effective studies. And, students require instructional materials in the latest diagnostic and therapeutic modalities to become competent practitioners.

We believe libraries are critically important in the process of transferring knowledge from the scientific record to health care practice. Without an effective health information delivery system our national health goals will not be easily achieved.

There are approximately 8000 health institutions consisting of more than 7000 community hospitals, over 550 colleges, universities and professional schools with medical, dental, nursing, veterinary, allied health and biological science programs, and approximately 470 medical research society, health care, business and industrial organizations serving the demands of 5 million health workers.

The achievements made possible through the MLAA, since its inception in 1965, are impressive. Over 1400 grants for research, resources, training, construction and publications have been awarded; and a network of eleven regional medical libraries designed to meet the needs of community health professionals wherever they may be practicing has been well developed and established.

This is not good enough. This is the time for increased efforts for innovative resourceful thinking and trials of new approaches. We are told we are entering a new era: the post-industrial revolution has begun and we are in an information age. Our technology has outstripped our wits to use and apply it. Our health libraries should be in the forefront working to advance medical and related sciences by aiding the dissemination and exchange of scientific and health information. But our health libraries are struggling to keep pace in the face of budgets that are barely adjusted to allow for inflation. The average medical book cost $18.92 in 1974 compared to $23.43 in 1977. The 1977 ALA Yearbook indicates book prices could go up by 50 - 60% by 1980. The average price of periodicals continues to increase inexorably, from $42.26 in 1974 in 1977.

The purpose of the MLAA is to supplement, not supplant local funding and project activity; yet it has been hampered in recent years by low funding levels. These have resulted in, or contributed to, moratoriums and termination of essential library programs which were so instrumental in achieving the progress to date. Inflation, of course, has magnified the effect of inadequate funding. For example, using 1970 as the base year and according to average consumer price indexes for medical care, MLAA allocations in 1977 should have been $10,250,000. just to keep pace with inflation. The actual 1977 appropriation was $8,000,000.

From 1971 to 1977, the funds appropriated constituted only 35% of funds authorized. It would appear that less than adequate attention has been accorded the original congressional intent in establishing the authorization levels. At the beginning of each year, approximately 68% of available funds are usually already committed to on-going projects, leaving only 32% of a small appropriation for new initiatives and new awards towards improving the transfer of knowledge from the research bench to practice.

PROGRAM RECOMMENDATIONS

RESOURCE GRANTS

Resource grants are an important part of MLAA. Improvement grants emphasize hospital library consortium development. The consortium grant program encourages better service, particularly in underserved areas and to physicians in isolated situations. However effective on-line electronic data base searching may be, unless the printed sources can be quickly, easily and reasonably obtained, information transfer does not take place.

An example of a resource project grant working towards the same objective is a cooperative information network in Mt. Auburn Hospital, Cambridge, Massachusetts. Beginning with the resources of this 300-bed community hospital, the health science collections of six local public library systems were strengthened and library and information services are being provided to health practitioners such as physicians, nurses, pharmacists, dieticians, and other health providers who had no effective access to the medical information system. The MLAA grant provides funds for administration, for training of reference librarians in public libraries in organizing and accessing health information, and for reaching the 5000 non-affiliated health providers in the area. The Library Services and Construction Act provides funds for resources to improve the public library health science collections, and state funds are used to serve the consumer of health information.

More such innovative and imaginative solutions to the delivery of health information is needed. The National Library of Medicine convened a colloquium in January of national figures knowledgeable in the needs of hospital libraries and the means for increasing the effectiveness of these links in the information chain. Their recommendations are concrete and practical and should be implemented.

Grants awarded under this section have encouraged new services such as clinical medical librarians, extension librarians serving rural areas, and improved library communications systems and technical processing activities. At the community hospital level, this program has strengthened core collections in barely adequate hospital libraries and has encouraged consortia arrangements. Considering that the 8,000 health sciences libraries are theoretically supposed to be reached through the $25 million allocated to this program over the past twelve years, it is understandable that this program has barely begun to satisfy the existing need.

A great deal needs to be accomplished. Many medical school libraries have been unable to implement library technologies that are considered standard in academic and public libraries such as OCLC-computerized cataloging, machine readable serial records, computerized circulation systems, computer output microfilm, and modern security systems. Some health sciences libraries still have antiquated equipment, worn furnishings, and are badly in need of remodeling.

RESEARCH PROGRAM

Relative to its importance, the Research Grant Program has been particularly underfunded, perhaps more so than any of the other MLAA authorities. In the twelve-year history of the MLAA's existence, less than 3% of the $90 million appropriated have been for research and development projects specifically in medical librarianship. The diffusion of these funds across the broad range of important researchable issues in the communication and information sciences has impeded breakthroughs (or, indeed, any real progress) on any one of these issues. Furthermore, because of appropriation limitations, programs with relatively short-term pay off have received negligible support.

From the perspective that health libraries are indispensable to education, research and patient care, and that librarians will remain as the key transmitters of biomedical research discoveries, additional funds to develop new and improved communication systems need to be made available nationally to encourage a strong research program.

The National Library of Medicine plans to direct greater efforts towards a higher quality research program and has called together an impressive group of advisors. Dr. Sherman of the American Association of Medical Colleges has reported to you on those initiatives. However, there are applied research needs within the library's smaller sphere that have been neglected. Of modest scope but significant need are such areas as the development of tools for analyzing information utilization, the development of methods for improving the allocation of scarce fiscal resources, the testing of the applications of newer technologies toward solving old problems, and the analysis of the information chain so as to make the most effective intervention approaches in the diffusion of knowledge.

SUMMARY

The health information delivery system in this contry is unparalleled. The on-line information system MEDLINE, and the regional medical library network developed by the National Library of Medicine are pioneering efforts. They laid the foundation for other systems and provided a model for other networks. But renewed emphasis on basics is now essential if we are not to lose the impetus gained over the past years. Training programs are needed to renew the profession and assure necessary leadership in the future. Research programs should be mounted to maximize the benefits of applications of technology. Resources support is essential for innovative means to improve the flow of information between the bench and the bedside. Mr. Chairman, we believe the continuity of this program is important. The information acquisitions process is a dynamic and little understood phenomenon. Better research, training, information delivery and effective resources maintenance are the sine qua non to quality health care. We recommend a 5 year renewal with appropriation levels at $15, $17 and $20 million.

Medical Library Association
Legislation Committee
Revised 2/24/78

MEDICAL LIBRARY ASSISTANCE ACT
1976 - 1983
(dollars in thousands)

PROGRAMS	Program Performance 1976	1977	1978*	Recommended Levels 1979	1980	1981-1983
TRAINING GRANTS	$1,389	$1,208	$1,418	$3,000	$3,000	$3,500
Number of Trainees	76	72	75	150	150	175
‡Number Trained by MLA	(1,556)	(1,921)	(2,000)	(2,500)	(2,750)	(3,000)
‡Number Trained by NLM	(160)	(240)	(300)	(350)	(350)	(350)
RESOURCE GRANTS	$ 726	$1,773	$1,632	$3,000	$4,000	$5,000
Number of Awards	44	66	48	125	166	200
‡Matching Funds	($1,500)	($3,500)	($3,500)	($6,000)	($8,000)	($10,000)
RESEARCH GRANTS	$1,353	$1,180	$1,046	$3,000	$3,000	$3,500
Number of Awards	17	15	12	40	35	40
REGIONAL MEDICAL LIBRARIES	$3,351	$3,086	$2,757	$5,000	$6,000	$7,000
Number of RML	11	11	11	11	11	11
Resource Libraries	90	90	90	90	90	90
Hospital Libraries	-	2,500	2,500	3,000	3,500	3,750
PUBLICATIONS/SPEC.SCI.PR.	$ 689	$ 847	$1,029	$1,000	$1,000	$1,000
Number of Awards	46	45	44	40	39	38
	$7,508	$8,094	$7,882	$15,000	$17,000	$20,000

‡Non grant supported activities
*Estimates

It is recommended that the Medical Library Assistance Act be renewed for 5 years, and that both appropriations and authorizations for FY 1979 through 1981 be set at 15, 17, and 20 million respectively. The program could level off at 20 million. The need for continuation of this vital library assistance program is attested by the growth of biomedical research publications, and public demands for health information. Any major health initiative results in increased demands for information. The transfer of technology is dependent on effective information delivery. The five year extension would secure the continuity of a proven, necessary program that has been recognized by legislators and by the health community.

Because of the low funding level over the past 10 years of the authority, the program has only been able to make grant awards to approximately 600 libraries. However there are over 8,000 health sciences libraries in the country. When the funding is increased to the recommended level, twice as many libraries on an annual basis will benefit directly from the program and perhaps five times as many institutions will benefit indirectly. The direct benefit results from the resource-sharing activity which is a primary objective of the library support programs.

The Regional Medical Library network consists of 11 regional libraries and 90 resource libraries. It's goal is to extend services to hospital libraries. Through the network approximately 2,500 hospitals have received RML services, but an additional 4,500 hospitals still need to be reached. A $15 million appropriation will enable health libraries to provide information services to a greater proportion of the country's health professionals.

Mr. **Maguire.** Thank you, Ms. Matheson, for your statement on behalf of the Medical Library Association.

Mr. Hitt, you are representing the Association of Academic Health Sciences Library Directors. If you would proceed.

STATEMENT OF SAMUEL HITT

Mr. **Hitt.** Thank you, Mr. Chairman, and members of the committee for allowing me to be here to testify today. I would like to concentrate on the need for supporting the training provisions in the Medical Library Assistance Act.

From the beginning of the MLAA in 1965 through 1974, when the training section of the act was discontinued, 516 library trainees were supported at a cost of approximately $7,380 per trainee. The need for trained biomedical librarians by 1974 had become somewhat alleviated. At the same time the MLAA training program was phased out, however, many advanced technological changes began to have a marked effect on medical library operations.

The specialized training need has today become acute in spite of impressive gains at various levels of training since 1965, including stepped up training initiated by the Medical Library Association and schools of library science:

One: The Medical Library Association in the past year trained 1,963 librarians in 33 different continuing education courses; in 1964 only 198 were trained in two courses.

Two: At least one biomedical library course is now taught in 46 of the 64 library schools accredited by the American Library Association. In 1965 these courses were taught in only 10 schools.

Three: As mentioned earlier, 516 trainees were supported between 1965 and 1974 by Medical Library Assistance Act funds.

Four: Currently the NLM trains 200 librarians annually on the use of Medline, a computerized reference service which did not even exist in 1965.

Five: A very large number of hospital librarians have been trained through the Regional Medical Library network, the regional medical programs, and the AHEC's.

These gains are not sufficient to meet specialized training needs. What any librarian needs to know to practice effectively today now covers so wide a spectrum that schools of library science are beginning to extend their master's program from 1 to 2 years.

For the biomedical librarian, the complex of skills required has become even more extensive in order to keep pace with the increasing complications involved in the delivery of health information. Consider the daily services and operations faced in the biomedical library today that require skills beyond the traditional ones—in services to the public:

One: The growing numbers of computerized data bases, all requiring initial and periodic update training—Medline and its 10 or more associated data bases, BIOSIS, NIIS, Psychological Abstracts, et cetera.

Two: The teaching skills necessary for sophisticated approaches toward educating the library user to effectively mine the library resources.

Three: The wide knowledge required to provide effective audio-visual services, which are increasingly becoming an integral part of the curricula of health schools.

Four: The innovations involved in delivering computer-assisted instruction, now also commonly in the curricula.

In library administration at all levels:

One: Knowledge of automated processes sufficient to plan and operate in-house projects such as automated circulation systems, serials control, acquisions and cataloging procedure, increasingly complicated library financial management, and the management of accessing such national cataloging data banks as the Ohio College Library Center.

Two: Development of expertise in such sciences as operations research and systems analysis, in order to plan and execute effective research and development efforts to improve methods of delivering health information.

Three: Knowledge of good management practices in all areas of library administration, including the effective utilization of statistical reporting techniques.

In order for already well-trained librarians to maintain pace with the many technological changes and to provide needed training at several levels, at least $3 million should be available in 1978 for the support of training programs such as these: (1) Library school training for biomedical librarianship; (2) practicum training in medical libraries in collaboration with schools of library science; (3) postgraduate internship; (4) training for hospital librarians; (5) development of skills in online search techniques; (6) the teaching skills for effective user education programs; (7) management of audio-visual services, and (8) management training.

Medical librarians have always been in the vanguard of devising better ways to deliver library services. Their ingenuity and their zeal will falter, however, if their knowledge and skills become insufficient to cope with the requirements of modern librarianship. And no matter how many dollars are put into medical library acquisitions, buildings, and equipment, these resources will be poorly accessed if library personnel are inadequately trained to provide services.

Thank you, Mr. Chairman. Now, I would like to introduce Mr. Al Brandon.

Mr. MAGUIRE. Thank you, Mr. Hitt.

Mr. Brandon?

STATEMENT OF ALFRED N. BRANDON

Mr. BRANDON. Thank you, Mr. Chairman.

My name is Alfred N. Brandon. I am librarian at the New York Academy of Medicine and director of the New York and New Jersey Regional Medical Library.

Through 11 regional medical libraries located throughout the country, information services are provided to health practitioners. Since the first Regional Medical Library was established in 1967, the number of libraries participating in the program has increased to over 2,500 without there being a comparable increase in authorization or appropriations for the Medical Library Assistance Act, the legislation that helps support this network.

Therefore, I strongly recommend that H.R. 10908, the biomedical research and research training amendments of 1978, which contains a renewal of the Medical Library Assistance Act, be considered at a minimum $15 million authorization level for 1979 and that appropriations equal the authorization.

Regional medical libraries comprise a national network through which health information available in one part of the country can be made accessible to a practitioner in another region. One of the major goals is to make data available as easily to the rural health scientists as to the health scientist in urban locations with many medical facilities available.

You can see from the listing in the testimony that the regional medical libraries were built using strong libraries, such as the Francis A. Countway Library in Boston; the College of Physicians in Philadelphia; The National Library of Medicine in Bethesda; the Biomedical Library, Center for the Health Sciences in Los Angeles, Calif., et cetera.

Building on these foundations allowed a decentralized program to be developed without unnecessarily duplicating resources. Each library is under contract with and funded by the National Library of Medicine to coordinate information services in its region. It should be noted, however, that the library's sponsoring institution is also helping to subsidize the program.

Recent annual expenditures for the regional medical library program have been inadequate to meet the demands being placed on it. 1977 expenditures were $3,086,000 and 1978 expenditures are estimated at $2,757,000. I recommend that in 1979 a minimum of $5 million be devoted to regional medical libraries, to allow them to reach their potential.

Exchange of information among libraries, which has been called interlibrary loan, has been the dominant regional medical library service to date. In New York and New Jersey nine labraries receive funds through the regional medical library to provide this service. However, Federal funds covered only 60 percent of their loans and we estimate that there is a great deal of additional sharing going on among libraries.

We also estimate that about 70 percent of the total interlibrary loan traffic is being supported by sources other than the National Library of Medicine.

The regional medical library program brings health sciences librarians together and under the RML umbrella many cooperative programs have developed. We have seen many consortia developing throughout the country where the hospitals that have severe budget problems have banded together to try through formal or informal consortia to share their resources. We have a number of these operating in the New York-New Jersey regional library program.

Consortia facilitate coordination of information services programs among the institutions and allow members to get more for the dollar.

Regional medical library staff members provide other services as well. They have a role in processing applications for NLM online data bases as well as in providing continuing education for data base users.

Educational programs such as seminars and other educational programs are being made available to different kinds of medical librarians, from the experienced to the completely untrained or the secretary in the hospital who has been asked to take on the responsibility of running the library.

The RML's are very strong in providing consultation services as needed for those setting up new libraries, developing audiovisual collections, or needing advice on any specific problem. We also give grant applicants assistance as best we can.

There are, however, several gaps in the program that need to be filled, and that can only be done, of course, with the additional funding for the program.

Regional reference services that parallel the existing interlibrary loan network need to be developed. Lists of materials available in each area need to be expanded to facilitate the sharing of resources. These locator tools enable the medical librarians to ascertain where particular periodicals and monographs are held and thus provide better service.

Information about the regional medical library program must be disseminated. There are about 2,500 hospital libraries using the RML program throughout the country, but there are another 4,500 that are not. We need a real outreach program to make those institutions knowledgeable about the use of the facilities that are available to them through the program.

In order to reach the goals established by the program and the needs expressed by the health care community, additional funds must be made available. I recommend that the Medical Library Assistance Act be renewed for 5 years and that both appropriations and authorizations for fiscal years 1979 through 1981 be set at $15, $17, and $20 million respectively.

The program has proved itself successful within its financial limits; it needs additional support to reach its full potential.

Thank you, Mr. Chairman, for this chance to testify.

Mr. MAGUIRE. Thank you.

Mr. Timour?

[Mr. Brandon's prepared statement follows:]

STATEMENT
of
ALFRED N. BRANDON
LIBRARIAN
THE NEW YORK ACADEMY OF MEDICINE and
DIRECTOR
NEW YORK and NEW JERSEY REGIONAL MEDICAL LIBRARY
before the

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES

March 3, 1978

My name is Alfred N. Brandon. I am Librarian at The New York Academy of Medicine and Director of the New York and New Jersey Regional Medical Library. Through eleven Regional Medical Libraries located throughout the country information services are provided to health practitioners. Since the first Regional Medical Library was established in 1967 the number of libraries participating in the program has increased to over 2,500 without there being a comparable increase in authorization or appropriations for the Medical Library Assistance Act, the legislation that helps support this network. Therefore I strongly recommend that H. R. 10908, the Biomedical Research and Research Training Amendments of 1978, which contains a renewal of the Medical Library Assistance Act, be considered at a minimum $15 million authorization level and that appropriations equal the authorization.

Regional Medical Libraries comprise a national network through which health information available in one part of the country can be made accessible to a practitioner in another region. Using existing strong libraries, which are located at the Francis A. Countway Library of Medicine, Harvard University, Boston; the College of Physicians, Philadelphia; the National Library of Medicine, Bethesda; the Shiffman Medical Library, Wayne State University, Detroit; the A. W. Calhoun Medical Library, Emory University, Atlanta; John Crerar Library, Chicago; Library of Medicine, University of Nebraska Medical Center, Omaha; University of Texas Health Science Center, Dallas; University of Washington Health Sciences Library, Seattle; Biomedical Library, Center for the Health Sciences, University of California at Los Angeles; and The New York Academy of Medicine, New York, allowed a decentralized program to be developed without unnecessarily duplicating resources. Each library is under contract with and funded by the National Library of Medicine to coordinate information services in its region. It should be noted, however, that the Library's sponsoring institution is also helping to subsidize the program.

Recent annual expenditures for the Regional Medical Library Program have been inadequate to meet the demands being placed on it. 1977 expenditures were $3,086,000 and 1978 expenditures are estimated at $2,757,000. I recommend that in 1979 a minimum of $5,000,000 be devoted to Regional Medical Libraries.

Exchange of information among libraries, interlibrary loan, has been the dominant Regional Medical Library Service to date. In 1971 there were approximately 315,000 documents supported by this program; in 1977 there were close to 450,000. But at the same time, demand has increased at a much greater rate than can be supported under the current appropriations for the Medical Library Assistance Act. For example, in New York and New Jersey there are nine libraries that receive funds to provide interlibrary loan. Between June 1, 1974 and May 31, 1975 these libraries filled 137,234 loans, but received funding for 82,535 or 60.1%. During the year that ran from July 1, 1976-June 1, 1977 a total of 122,227 loans were filled of which there was support for 72,911 or 59.7%. And a great deal of sharing is going on among hospital libraries for which we have no statistics. In all, we estimate that about 70% of the total interlibrary loan traffic is supported by sources other than the National Library of Medicine. Continued and adequate support for this service is essential to information transfer. It is important that the nurse working in a 75 bed community hospital or rural clinic have the same access to materials as the researcher in a major medical center. This program provides the access.

The Regional Medical Library Program brings health sciences librarians together and under the RML umbrella many cooperative programs have developed. Libraries, especially those in hospitals, have been subject to severe budget restrictions. Out of necessity and with the help of the Regional Medical Library, consortia or local sharing arrangements have developed. By working in groups, libraries can cooperatively acquire materials to be used by all. An example of such an arrangement is the Consortium of Hospital and Rehabilitative Geriatric Enterprises or CHARGE. The consortium, originally set up with funds provided under the Medical Library Assistance Act, works out of Mulhenberg Hospital in Plainfield, New Jersey. An audiovisual center was established at the Hospital to provide resources to ten nursing homes in the area. About 100 items (16mm films, filmstrip cassettes and projectors) are available to be borrowed by nursing home staff as needed. Nurses and nurses aides as well as housekeeping and security staff members have been using the materials. Calls to the hospital library can also be made to obtain answers to other questions that arise in the course of a day's work.

Regional Medical Library staff members provide other services as well. They have a role in processing applications for NLM on-line data bases as well as in providing continuing education for data base users. Educational programs are made available to librarians working in medical schools, research centers, hospitals and community agencies. Consultation services are available to those setting up new libraries, developing audiovisual collections or needing advice on a particular problem. Grant applicants can turn to the RML for assistance.

Several gaps in the program need to be filled, but this can only be done with additional funding for the program. Regional reference services that parallel the existing interlibrary loan network need to be developed. Lists of materials available in each area need to be expanded to facilitate the sharing of resources. And, although there are many participants in the network, additional funds are needed to make the program more widely known to facilities that do not have professionally trained, full-time librarians.

The existing Regional Medical Library Network provides the framework for provision of information services to health practitioners. But in order to reach the goals established by the Program and the needs expressed by the health care community, additional funds must be made available. A $15 million authorization for Medical Library Assistance Act programs is a beginning.

Thank you for the opportunity to present testimony. I will be pleased to answer any questions and provide you with additional information.

# # #

STATEMENT OF JOHN A. TIMOUR

Mr. TIMOUR. My name is John Timour. I am privileged to represent the American Library Association in support of a 5-year extension of the Medical Library Assistance Act.

I would like to summarize very briefly the reasons for the American Library Association's concern with this act [see p. 436]. The regional medical library program funded through the Medical Library Assistance Act, as Mr. Brandon pointed out, does, in fact, support unaffiliated health practitioners and students, so that those who are not now in institutions providing library services, can go to their library, and can access through the network the material relevant to their studies, to their research and to their practice.

Second, in the field of consumer education, public libraries need not acquire vast amounts of health science material, most of which is much more expensive than the general run of literature and information.

They can access on behalf of those people, who are concerned with health and health care for their families, material relevant for their informational needs directly from the medical library network.

The last point that I would like to make is that through the consortium development, different types of libraries have come together and begun to discuss common problems, share information, and, in fact, cooperate to an extent which they have not done before.

For example, in my own State of New Jersey, Rutgers Medical School is attempting to create a South Jersey Medical School without walls. The hospitals concerned, through a Medical Library Assistance Act resource grant, created a consortium and began to share information, began to share services, began to have and initiate dialog which will, at least in part, contribute to the success of the medical school.

In the city of Rockville, Conn., where I was before coming to the Philadelphia area, a Medical Library Assistance Act grant to the Rockville General Hospital enabled them to establish on their own intitiative a reading list in the physicians' lounge of books appropriate to the layman in treating chronic diseases like emphysema, cardiac problems, and so on.

These books were reveiwed by the physicians for their clinical and appropriate content. In turn they were recommended for purchase by the public library where they were checked out to the individual patients on a prescription basis, much as drugs are prescribed for those needing that particular therapy.

In conclusion, I would like to reemphasize the fact that the American Library Association is in support of the Medical Library Assistance Act and would recommend a 5-year extension simply because we are facing a White House Conference in 1979, and for the first time a disparate group of library users and librarians will be gathering together to discuss common problems. In addition, the library photocopying provisions of the new copyright law will be reviewed in 5 years. Those two factors, we think, will contribute to making a 5-year extension of this act a reasonable time period during which problems common to all types of libraries might, in fact, begin to be resolved.

Thank you very much.

[Testimony resumes on p. 442.]

[Mr. Timour's prepared statement follows:]

Statement of John A. Timour
University Librarian
Thomas Jefferson University
Philadelphia, Pennsylvania
before the
Subcommittee on Health and the Environment
House Committee on Interstate and Foreign Commerce
on HR 10908
Biomedical Research and Research Training Amendments of 1978
March 3, 1978

My name is John Timour. I am University Librarian at Thomas Jefferson University in Philadelphia, the largest private medical school in the country. As an academic health sciences librarian, I am pleased to be here today on behalf of the American Library Association in support of extension of the Medical Library Assistance Act (MLAA).

When Congress enacted the Medical Library Assistance Act in 1965 it recognized the vital public interest in effective and timely delivery of health information. In few areas of library and information work does the need for quick and comprehensive response to information requests occur so often, or have such direct consequences for human life and welfare. That public need and interest, recognized by the passage of MLAA in 1965, continue to exist today.

Worthy of particular comment is the important work done by the regional medical library program. Under this program the nation is organized into eleven regions. Through contracts with libraries in these regions, the development of multi-state health information networks and the cooperative use of resources has been initiated and supported. Some typical services offered or facilitated by these regions include rapid communication systems, document delivery and interlibrary loan, document location information, computerized reference services, and coordination of resource development.

In 1976 alone, the regional medical library program provided partial funding for 500,000 interlibrary loans. While it should be recognized that the state and local governments, public and private institutions, carry a significant proportion of the costs of health information delivery (it is estimated, for example, that another 1.5 million interlibrary loans in health information are not federally supported), the multi-state and multi-institutional nature of this network make federal funding the only assured basis for their continuing support. This subject-specialized network will be an essential building block in the developing general state and national information networks.

In Florida, for instance, three health science libraries (at University of Florida, University of Miami, and University of South Florida) serve as resource libraries to give health professionals access to medical resources regardless of location. Through this MLAA-assisted biomedical network approximately 2,000 journal articles a month are delivered to Florida health practitioners who request items through their local hospital library or public library. Most requests are from physicians with specific patient problems requiring reference to medical literature which the hospital library does not own.

Under a special MLAA grant through the regional medical library serving New York a coordinated acquisitions program has been established. It was discovered that due to financial stringency many medical libraries were discontinuing subscriptions to lesser used journals and neglecting to subscribe to new ones. Under this program the libraries have planned regionally who will be responsible for retention of certain journals. This procedure will assure that important resources are not lost to the region, and that new publications are available within the region. The purpose is to keep regional resources strong.

How such regional planning and coordination will be affected by the new copyright law which took effect on January 1, 1978 is not yet certain. In balancing the rights of copyright proprietors and users of copyrighted material, the law places limitations on the making of photocopies in lieu of interlibrary loan. This may affect the ability of small hospital libraries to serve their users. Your subcommittee, with jurisdiction over the Medical Library Assistance Act, seems to us to be the logical place for monitoring the impact of the copyright law on medical libraries. We stand ready to be of whatever assistance we can.

MLAA programs have followed a logical progression in the development of a comprehensive medical information system. In addition to the establishment of Regional Medical Libraries, MLAA resource grants have been used to help improve the resources of medical libraries, and to establish libraries in institutions without them. This step brought health resources closer to the user, and helped to relieve the demands on the Regional Medical Libraries. Recently, the resource improvement grants under MLAA have emphasized hospital library consortium development. The consortium grant program encourages better service and wider availability of biomedical information and research resources by supporting groups of libraries in institutions such as hospital, mental health centers, research institutes, clinics, community colleges, and public libraries.

A consortium grant in my own state involves 21 institutions, of which three are general academic, 17 are health related, and one, the Chester County Public Library, is a public library. Administered by the Crozer-Chester Medical Center, this is a resource-sharing project in which the materials held by any one library are accessible without charge to all the others. The two-year MLAA grant provides for a project director, for administration, and for some collection development in the health science libraries of the consortium.

Other resource grants are project grants. A recent example is an innovative cooperative information network in Cambridge, Massachusetts. Through the resources of Mt. Auburn Hospital and the strengthened health science collections of six local public library systems, library and information services are being provided to health practitioners not affiliated with medical schools or hospitals. Such non-affiliated physicians, nurses, pharmacists, dieticians, and other health providers had previously had no effective access to the medical information system. The MLAA grant provides funds for administration, for training of reference librarians in public libraries in organizing and accessing health information, and for reaching the 5,000 non-affiliated health providers in the area. The Library Services and Construction Act provides funds for resources to improve the public library health science collections, and state funds are used to serve the consumer of health information.

Another project grant in New Jersey is called CHARGE--the Consortium of Hospital and Rehabilitative Geriatric Enterprises. This fancy name provides a very down-to-earth and much-needed service. Muhlenberg Hospital in Plainfield has established an audiovisual center to provide audiovisual medical resources to ten nursing homes. About 100 items (mostly 16mm films, filmstrip cassettes and projectors) are available to be borrowed by nursing home staff as needed. The materials have been used mostly by nurses and aides, but also by housekeeping and security staff. Now in its second and final year of MLAA funding, CHARGE has begun charging modest dues to the nursing homes as a means of continuing the project after federal funding ends.

Additional projects of this type deserve funding if medical information services are to be extended to areas and individuals so far underserved. All the MLAA programs--applied research, training, resource building, information delivery, research dissemination--are essential to the continuation and development of an effective health information system.

A three year extension of MLAA, as proposed in HR 10908, is the minimum length of time this important library program should be extended . The American Library Association recommends a five-year extension. The provision of health care information is so essential to the welfare of the nation's citizens that a five-year extension is appropriate. To ensure maximum continuity where multi-year projects are involved, to allow potential recipients of funds to plan adequately, and to make the most efficient use of federal dollars, a five-year extension of MLAA is recommended.

In the years since 1965 the programs authorized under MLAA have demonstrated flexibility and responsiveness to need. Federal appropriations to this program have not kept pace with inflation nor have they been adequate to need. The American Library Association recommends authorization levels of $15 million for FY 1979, $17 million for FY 1980, and $20 million for FY 1981, as proposed in S.2450, rather than the $15, $16, and $17 million in HR 10908.

We recommend these modest increases over the amounts in the House bill for several reasons. Medical resources are very expensive. The 1977 average price of a medical periodical was $51.31. In contrast journals in the humanities, social sciences, and recreation averaged less than $12.00. Medical audiovisual materials are also expensive, but often make clear for diagnostic or educational purposes something that pages of text could not illuminate.

Computerized information retrieval, also a costly item, has become essential as the amount of material about health and disease has grown. The major reason for this rapid increase has been a commitment by the United States to biomedical research and to the improvement of the health care of our citizens. However, the size and complexity of the medical information system now poses problems in itself. The challenge to information scientists and librarians is to provide accurate and timely access to the level and portion of this vast knowledge needed by an individual practitioner, educator, or scientist. We feel there is a federal obligation to support dissemination of knowledge generated through federal support of biomedical research. Increased support of MLAA would help achieve this goal.

The contribution of the Medical Library Assistance Act in the development of a national medical information system is an essential component of a national system of interlibrary cooperation and library networking in all subject areas. These developments will be an important item on the agenda of the White House Conference on Library and Information Services to be held in October 1979. However, it will take many years beyond the White House Conference before we can expect more than the skeletal outline of a national consensus for library cooperation and sharing. The dialogue between public and health science libraries has just begun. MLAA has been successful, but the needs have never been greater.

In conclusion, we strongly support extension of the Medical Library Assistance Act, and we are pleased that your subcommittee has acted to renew the program. We recommend a five-year extension of MLAA at authorization levels of $15 million for FY 1979, $17 million for FY 1980, and $20 million for FY 1981.

We appreciate this opportunity to present the views of the American Library Association to the subcommittee.

Mr. Maguire. Thank you very much, Mr. Timour.

Mr. Preyer?

Mr. Preyer. I want to thank all of you for being here, and I hope that you will forgive me if I give Dr. Hitt an especially warm welcome, since he is from the University of North Carolina.

I was reading Carl Ginn's book, "The Garden of Eden," and he closes that book, the last page of it, saying how difficult it is in the modern days to focus our attention on real hard knowledge, scientific knowledge. He says that the pseudosciences have taken over: the Bermuda Triangle, Close Encounters, and the like.

He is very concerned that we are getting away from basic research and real learning. It points up the problem we have in funding this kind of information here, where we still have a lot of the corporate board mentality, and the Nixon administration, particularly, came down hard. It has to be applied just like a Band-Aid. It has to be merchandised. It has to be shown to work before you can get funding for it. I hope that we are getting away from that attitude.

But getting sufficient funding for programs that do not have an awful lot of political sex appeal is a real problem, and your testimony here, your information, will certainly go a long way toward helping us get additional funding.

The 5-year extension may be a problem for this committee because we traditionally have gone 3 years in the Commerce Committee, and it is pretty hard to get through the committee with a 5-year bill.

Let me ask you one question, since we are about to have to go to vote now. Do any of you have any comments on the provision in the bill which would provide for the appointment of members of the board of regents by the Secretary of HEW or the President?

The chairman wanted to change that to make sure that where appointments were made they were not being made with any down-

Ms. Matheson. I think that the Medical Library Association would support that change very strongly. There have been troubles, as you know, with timely appointments to the board of regents, which has caused, particularly this year, a situation where grants have not been awarded because of the lack of a board. We are very strongly in favor of the change.

Mr. Brandon. I would second that.

Mr. Timour. The American Library Association would support that position.

Mr. Preyer. Thank you.

Thank you, Mr. Chairman.

Mr. Maguire. Thank you, Mr. Preyer.

I would like to express my gratitude to all of the witnesses, and I am glad to have such fine representation from New Jersey.

I thank all the panels for their presentation. Several individual organizations have requested that their testimony be included in the record of this hearing. I ask unanimous consent that the statement of the Red Cross, Council of Community Planning Center, the American Academy of Pediatrics, Juvenile Diabetis Foundation, American College of Chest Physicians, American Association of Colleges of Nursing, and the Hemophilia Foundation and other organization which have made a request that their statement be included in the hearing record.

Is there objection? There being no objection, it is so ordered.

Thank you all very much, and the hearing is concluded.

[The following statements and letters were received for the record:]

STATEMENT OF
JOSEPH C. ROSS, M.D., F.C.C.P.
PRESIDENT OF THE AMERICAN COLLEGE OF CHEST PHYSICIANS

SUBMITTED TO
SUBCOMMITTEE ON PUBLIC HEALTH AND THE ENVIRONMENT
OF
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES
CONGRESSMAN PAUL G. ROGERS, CHAIRMAN

Re: Expiring Authorizations
of the
National Heart, Lung, and Blood Institute

March 3, 1978

Mr. Chairman and Members of the Subcommittee:

My name is Dr. Joseph C. Ross, and I am Professor and Chairman, Department of Medicine, Medical University of South Carolina. I am also the President of the American College of Chest Physicians. It is my pleasure to represent this professional medical specialty society which is composed of more than 10,000 heart and lung medical specialists.

I would like to take this opportunity to express our gratitude for your having afforded us the opportunity to submit our views on legislation to extend the legal operating authorities of the National Heart, Lung, and Blood Institute and the National Research Service Awards Program. We appreciate this early effort on your part in introducing "The Biomedical Research and Research Training Amendments of 1978". We hope that the momentum created by the introduction of H.R. 10908 will insure its swift passage by the Congress so that the Institute may continue to function smoothly prior to the time that the operating authorities, mandates, programs, and policies of NHLBI are substantially revised.

For more than 50 years, heart and blood vessel diseases have been major causes of death in this country, accounting for over 50% of all deaths annually, nearly three times the number of deaths from cancer, the next highest cause.

Lung diseases themselves have become a very serious public health problem. As the 6th leading cause of death in the United States, lung diseases account for more than 160,000 deaths each year, 60 million days lost from work, and 40 million days of restricted activity; in addition, pulmonary disease costs the economy approximately $6 billion annually in lost productivity and wages and medical care costs.

As you well know, it was 7 years ago that the research mandate of the Institute was expanded to include the lung and that a concerted strategy was initiated to meet this very serious health problem. The NHLBI and the biomedical community have worked together quickly and effectively to lay the foundation for the many research programs presently conducted under the auspices of the NHLBI.

However, in order for Americans to reap the full benefits from this initiative, the Institute must be given adequate time to nurture these programs. Biomedical research projects, training grants, and clinical trials are primarily long term programs. One-year renewals hinder the task of planning these long-range activities. The Division of Pulmonary Disease, established in 1970, now has the momentum to affect the diagnosis, prevention and treatment of lung diseases. Also, short-term renewals do not provide sufficient time for the Institute's long-range research undertakings to mature to the point where Congress can effectively evaluate them.

Without the continuity that a three-year extension provides, the Institute could have extreme difficulty recruiting and retaining highly qualified research manpower -- indivuduals who may not be willing to involve themselves in short-range projects. It is for the above cited reasons that the American College of Chest Physicians is extremely pleased that H.R. 10908 proposes that the operating authorities of the Institute be extended for three years.

However, in your remarks accompanying the introduction of "The Biomedical Research and Research Training Amendments of 1978," you qualified your proposal for a three-year extension by mentioning that "the second and third years of authorizations for these programs are included in the bill for the purpose of receiving comments from outside interested parties on the future authorization level for the programs." The College sincerely hopes that these remarks are directed solely at the authorization levels themselves and are not indicative of wavering support for extending the operating authority for the National Heart, Lung, and Blood Institute for three years.

The College is firmly committed to the proposition that a three-year extension for the NHLBI is essential not only for the Institute to effectively conduct its biomedical research and prevention education, and control programs, but more importantly, as indicative of Congress' unrelenting commitment to search for new ways to prevent, detect, and control cardiopulmonary and cardiovascular diseases.

In regard to the authorization levels, the College respectfully requests the following authorizations for the NHLBI. For FY 1979, the College proposes an authorization of $600 million of which $50 million should be allocated to prevention, education, and control programs. For FY 1980, we recommend $660 million for the Institute's research and training activities, of which $55 million should be allocated for PEC programs. Finally, the College requests on authorization of $730 million for FY 1981, of which $60 million should be designated for PEC programs. While these figures may, at first glance, appear high, we note that, under the Public Health Service Act, only 15% of these funds may be allocated to pulmonary research and training activities.

The American College of Chest Physicians is concerned that the authorization levels included in H.R. 10908 are not sufficient to provide for an expanded research effort in cardiopulmonary medicine. In your Report that accompanied H.R. 4975 last year, you applauded the National Heart, Lung, and Blood Institute for taking a major initiative in promoting prevention, education, and control programs:

> These programs are the primary means of disseminating information to the public and the health profession concerning important factors in the prevention of these diseases and the Committee strongly believes that these programs should be augmented.

Our recommended prevention, education, and control authorizations are consistent with this wise proposition. We strongly believe that the Institute has made valuable inroads in cardiopulmonary research. It is significant that the Institute has received 25% more research grant applications in FY 1977 than in FY 1976. It would be discouraging to the biomedical research community, and the American public which benefits from their advances, if this enthusiasm to conduct heart, lung and blood research were met by an allocation of funds insufficient to meet these challenges.

The NHLBI's Division of Lung Diseases intends to fund important research projects in lung cell biology, pulmonary vascular disease.

chronic bronchitis and emphysema, pediatric pulmonary disease, and respiratory failure. The Division of Heart and Vascular Diseases will fund critical projects in hypertension, cerebrovascular disease, cardiovascular disease, arrythmias, and congenital and rheumatic heart disease. And while we are pleased with the efforts of the Pulmonary Diseases National Research and Demonstration Center at the University of Vermont, it is distressing to note that this is the only pulmonary center thus far established, although authority exists for the establishment of ten such lung centers. Without a substantially increased authorization and appropriation, there can be no further expansion of these important centers for applied research.

The opportunity to develop these crucial research and prevention, education, and control programs in cardiopulmonary disease is at hand, but the ability to do so far exceeds the resources that have been made available for the implementation of the National Program. The College feels that, in light of the extension of Section 419B of the 1972 Act which includes the 15% reservation of sums appropriated for NHLBI for lung disease, the Institute can make significant progress in combatting cardiopulmonary disease at the authorization levels we recommend.

Before concluding our comments, we would like to express our support for two other amendments to the NHLBI authorities which are proposed in H.R. 10908. §202 (a) of your measure would require the annual reports of the NHLBI Director and the NHLBI Advisory Council to be transmitted to the Congress no later than November 30 of this year. This intelligent and reasonable amendment, if enacted, will allow the Health Subcommittees and the Appropriations Committees access to a resource which will be valuable in ascertaining the coming year's legislative activities and funding levels. H.R. 10908 also amends §412 of the Public Health Service Act to provide for the dissemination of information regarding factors affecting the prevention of heart, lung, and blood diseases in a more timely and efficient manner. As an organization representing thousands of medical practitioners, ACCP supports this effort to translate research advances into actual patient care. Finally we would like to express our enthusiastic support for § 204 of H.R. 10908, which requires heart, lung, and blood centers to engage in continuing education programs for health professionals.

Mr. Chairman, and distinguished Members of this Subcommittee, on behalf of the more than 10,000 members of the American College of Chest Physicians who specialize in treating diseases of the heart and lungs, I wish to express our deepest appreciation for your having invited us to present our views on this important legislation pending before your Subcommittee. In the spirit of mutual cooperation and support, it is our hope that you will continue to call upon us for advice and consultation whenever you think we can be helpful to you and this Subcommittee.

The American Sociological Association

Comments made at a Public Hearing of the Committee on a Study of National Needs for Biomedical and Behavioral Research Personnel, National Research Council, Commission on Human Resources, February 9, 1978, Washington, DC.

Paul Williams, Director, Minority Fellowship Program
Russell R. Dynes, Executive Officer

The American Sociological Association wishes to commend the Committee for its report on Personnel Needs and Training for Biomedical and Behavioral Research. Our comments here are necessarily brief and focused primarily on one aspect of the report.

On the overall report, we endorse the recommendation that the Federal Government continue to support and maintain both training grant and fellowship programs in the biomedical and behavioral sciences. In addition, we support a gradual shift toward post doctoral support, particularly if institutional dislocation due to program change is minimized. We support the concept and increased funding of Midcareer Research Training as an appropriate step to increasing research personnel in priority fields.

While there are many aspects of the report which demand close attention, the Association commends the special concern given in the report to minorities. We will direct the remainder of our comments to this specific concern. The American Sociological Association is one of five professional organizations that have graduate fellowship programs for minority students supported by funds available through the National Research Service Award Act. Our program, although relatively new, was the first of these, and we are confident that we have begun to deal with some of the problems that led to its initiation. The number of minorities holding advanced degrees in sociology remains woefully inadequate and much more needs to be done. However, during the short life of this program we have provided assistance to some 120 graduate students. By some estimates, this is equal to about one-third of the minorities who currently hold the doctorate in the field. At present, seventy-five students are receiving support.

The report makes two specific recommendations with respect to the support of the training of minorities: (1) that predoctoral support be provided beginning with the first rather than the third year of graduate training; and (2) that special efforts be made to encourage minorities to undertake post doctoral training through the establishment of special fellowship programs targeted toward them. We would like to endorse these recommendations and to make one or two additional points relating to them. First, there is an obvious need to identify and support minorities who are likely to be successful in graduate and professional training early in their academic careers. Ideally, this would be sometime during the undergraduate years. Short of this, however, first year graduate support is an absolute must. A part of our success is undoubtedly due to the fact that we have been able to obtain a relaxation of the policy that restricts support to later years. On the other hand, a policy that can have the effect of cancelling out much of this success is the requirement that support be limited to a total of three years. The 1976 report of the National Board on Graduate Education on Minority Group Participation in Graduate Education indicates that the median time required for students to be registered in graduate school before they receive their doctorates--and this applies to whites and non-whites--is approximately six years. Thus, we strongly recommend that the Committee not only endorse the provision of support for minorities in the first two years of their studies but that it also encourage that provisions be made for five to six years of support as well.

With respect to the second recommendation, we have two observations. First, it encourages special efforts to promote post doctoral training. There will be a need for special efforts to identify and encourage qualified minorities to undertake predoctoral training as well. Through our program we have confirmed that there is a supply of talent available to undertake predoctoral training. At the same time we have also become aware of the continuous need to stimulate applications from these persons and to work with them throughout their years of predoctoral training in order to insure their success. We also believe, in this connection, that the ASA Fellowship Program, and the other programs supported by NIMH, can serve as models for post doctoral efforts and for similar programs in other disciplines.

Ours is an institutional grant to support predoctoral training. We encourage you to support the continuation of institutional grants, and recommend further that programs designed for minorities be excluded from consideration when pre/post doctoral ratios are being calculated.

There is one final point that we would wish to make. The report suggests that there is an interest in having nongovernmental resources become more heavily involved in the training of Biomedical and Behavioral Research personnel. Our program is designed to do just this. We foster, through tuition remissions, arrangements for research and teaching assistantships, and a variety of other devices, the sharing of the costs of training with public and private institutions. About one-fourth of trainee costs are now being borne by the universities involved. We have also involved a private foundation. Policies that encourage these and similar arrangements should be encouraged.

As a final comment, we appreciate the data collection efforts of the Committee which we find invaluable and we would hope would be continuous, so that longitudinal data can be used as a base for policy in the future. Aggregate data, however, sometimes has a tendency to gloss over the problems of special groups and categories. We would encourage the Committee to continue in the future to give specific attention to the needs of minorities.

STATEMENT OF
MRS. ERWIN J. LURIE, PRESIDENT
JUVENILE DIABETES FOUNDATION

SUBMITTED TO
SUBCOMMITTEE ON PUBLIC HEALTH AND THE ENVIRONMENT
OF
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES
CONGRESSMAN PAUL G. ROGERS, CHAIRMAN

Re: Expiring Authorizations
of the
National Heart, Lung, and Blood Institute

March 20, 1978

Mr. Chairman and distinguished members of this committee, I am Caroline Lurie, international president of the Juvenile Diabetes Foundation. I am also the parent of a 21 year old son who has had diabetes for almost 12 years. JDF is an international voluntary health organization four and a half years old, dedicated to supporting and furthering research and education in the field of Diabetes. I submit this testimony to you on behalf of our board of directors and the our entire membership and their families with over 100 chapters throughout the United States, Canada and Israel.

On July 23, 1974 the National Diabetes Mellitus Research and Education Act (P.L. 93-354) was enacted. This legislation, which you, Congressman Rogers, sponsored, increased attention at the Federal level for efforts to combat diabetes. This Act authorized the expansion of programs for the development of Centers for research and training in diabetes. It also mandated the establishment of a Diabetes Mellitus Coordinating Committee composed of representatives of the various institutes of NIH and other Federal agencies involved in research. Finally, it provided for the creation of the National Commission on Diabetes to formulate a Long-Range Plan to combat diabetes.

Two years ago after receiving the recommendations of the Congressionally created National Commission on Diabetes you, Congressman Rogers and other Distinguished Members of our Congress, took on the challenge and responsibility of initiating the unique, Long-Range Plan to combat diabetes. You fostered an attack on a disease that had become a major and devastating health problem facing our Nation.

One unique aspect of this long-range plan to combat diabetes is its comprehensiveness. Diabetes must be encircled from every available vantage point, using every available resource. In the National Heart, Lung, and Blood Institute, under the capable and innovative leadership of Dr. Robert Levy, we have one such vital resource to combat diabetes.

Diabetes has been found by the scientists to be one of the four major causes of heart disease. The majority of diabetic deaths are due to cardiovascular disease. About 25% of diabetics are under treatment for heart disease. Accordingly, the Juvenile

Diabetes Foundation deems it imperative for Congress to adequately support the research and training activities of the National Heart, Lung, and Blood Institute.

Congressman Rogers, we commend you for introducing H.R. 10908, the Biomedical Research and Research Training Amendments of 1978, a bill which provides for a three-year extension of appropriations authorizations for the NHLBI. The Senate counterpart to this measure (S. 2450) provides only a one-year extension of authorizations for this vital Institute. JDF considers the three-year extension as the essential feature of this legislation. It is indicative of strong Congressional support for the Institute. The unstable and unpredictable atmosphere generated by repetitive one-year renewals can only have deleterious effects on the Institute's ability to carry out its Congressional mandates.

Although we approve of the three-year extension for the NHLBI, JDF considers the authorization levels provided in H.R. 10908 to be too low for the Institute to initiate new inroads in researching the interrelationships of diabetes and cardiovascular diseases. At authorization levels of $460 million, $550 million, and $550 million for fiscal years 1979, 1980, and 1981, the Institute will find it difficult, if not impossible, to initiate new research and training programs while at the same time meeting its existing commitments.

The NHLBI has shown a commitment to meet your mandates. Between FY 1975 and FY 1978, the NHLBI has more than doubled its funding of diabetes research and training activities. Dr. Levy has stated that "... diabetes is clearly an independent risk factor for coronary heart disease, sudden death, congestive heart failure, stroke and peripheral vascular disease..." Due to these realizations, there has developed, "enormous investigator interest in diabetes." The NHLBI has received approximately 25% more research grant applications in FY 1977 than in FY 1976; a great portion of these applications relate to the cardiovascular complications of diabetes. We are faced with increased enthusiasm in the scientific community to participate in the research programs of the NHLBI, but insuffcient funding available for the Institute to meet this challenge.

The National Heart, Lung, and Blood Institute has proven itself to be an effective and efficient vehicle for obtaining new knowledge regarding the causes and prevention cardiovascular disease. This is a necessary component of the Long Range Plan to Combat Diabetes. Accordingly, the Juvenile Diabetes Foundation respectfully requests that H.R. 10908 be amended to include the following authorization levels:

FY 1979: $565 million for research and training programs
$ 50 million for prevention, education and
control programs.

FY 1980: $672 million for research and training programs
$ 75 million for prevention, education and
control programs.

FY 1981: $754 million for research and training programs
$100 million for prevention, education and
control programs.

The Juvenile Diabetes Foundation would also like to express its support for one other important amendment to the National Heart, Blood Vessel, Lung, and Blood Program which is embodied in H.R. 10908. §203 of the bill would amend §413 (d) of the Public Health Service Act "to provide on a timely basis "for the disemination o research information to the public and health professionals. The speedy transmission of cardiovascular advances "from bench to bedside" can save literally thousands of lives of diabetics, patients who are particularly susceptible to cardiovascular complications.

CONCLUSION

The Juvenile Diabetes Foundation believes it is incumbent on this Congress to carry the Long-Range Plan for diabetes forward from its belated beginning to its hopeful end. In the National Heart, Lung, and Blood Institute, we have one significant component for the attack on this devastating disease. Therefore, JDF urges Congress to support the three-year extension of this vital Institute at our recommended authorization levels.

If we of the Juvenile Diabetes Foundation seem impatient, it is because time for a diabetic is measured differently. Five years of clinical research in a laboratory is not a luxurious amount of time, but five years in the life of a diabetic can bring on the physical and emotional chaos of heart disease at a frighteningly accelerated pace which abbreviates the human life span.

Despite progress that has been made due to your farsighted awareness and generosity, we are still far from the primary goal of eradication -- or even optimal effective management of the disease. It is therefore essential that scientific research -- research like that conducted by the NHLBI -- continue to be enhanced, expanded and intensified in order to improve treatment of this disease, to seek a means of preventing its devastating complications, and to ultimately find a cure.

Thank you for the opportunity of formally presenting our views to you and your distinguished colleagues.

February 20, 1978

Boca Raton Community Hospital, Inc.

The extension and increased funding of the Medical Library Assistance Act is of prime importance to Boca Raton Community Hospital and biomedical libraries throughout Florida. The MLAA provides funding for library and information services, regional medical library training and resource projects. It acts to improve the quality of health care in the United States by providing for the rapid transit of needed biomedical information to physicians and other health professionals, wherever their location, through its programs.

The Medical Library Assistance Act fills many needs for us and others in this area. One of the most important of these needs is in the area of interlibrary loans. It is just not feasible for the average hospital library to have an extensive book and journal collection because of limitations in both budget and space. However, books, and especially journals because of their currency, are one of the most important means of dispensing the tremendous amount of continually-growing information in the health care field. Because of the nature of the "information explosion", the results of many new treatments and research are being published in hundreds of journals from all over the world. It is imperative for quality medical care to be able to have access to all or to at least a majority of these journals, simply because needed information on a specific topic may be found in no other place.

Because of this need for access to so many journals, Boca Raton Community Hospital and others like us must depend on borrowing from other libraries to meet our information needs and thus ultimately patient needs. Through the MLAA, we are able to borrow the items we need--working through the University of Miami Medical School Library and regional network--until our quota of interlibrary loans is filled. Once over the quota, we are charged 3.50 per each additional request. Without the MLAA, each request would be assessed a charge--a significant factor in the limited budget of most hospital libraries.

In addition to an extension of the Medical Library Assistance Act, an increase of funding is necessary to carry out needed regional training and resource programs (such as interlibrary loan service). No funding increases have been received in the last four years as costs have continued to rise, and many programs are being curtailed because of this. A curtailment of interlibrary loan service, as is being discussed, would have a disastrous effect on community hospital libraries.

Without the benefits of the Medical Library Assistance Act, community hospitals and their patients would certainly be handicapped. The many programs the MLAA sponsors help to assure that biomedical information is dispersed throughout all areas of the country and state--including ours--rather than being concentrated in only a few areas or not being available at all when it is needed. I feel that a lack of MLAA programs would adversely affect the quality of health care available to patients in the United States and in our area.

Julia L. Andrews

Julia L. Andrews
Medical Librarian

800 MEADOWS ROAD • BOCA RATON, FLORIDA 33432 •

CEDARS-SINAI MEDICAL CENTER

Reply to:
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Direct Dial Number:

February 27, 1978

Honorable Paul G. Rogers
Chairman, Subcommittee on Health
and the Environment
Room 2415
Rayburn Building
Washington, D.C. 20515

Dear Mr. Rogers:

As a practising hospital librarian, I would like to support the renewal of the Medical Library Assistance Act and would appreciate having this letter made a part of the hearing record.

Since its passage in 1965, the Medical Library Assistance Act has resulted in the establishment of a functioning network of medical libraries sharing resources and disseminating information. Utilizing a network of ninety resource libraries and thousands of small libraries, the eleven Regional Medical Libraries, which received funding for training, consultation and document delivery, have brought the results of research within the easy reach of large numbers of health professionals. It is important that this information be rapidly and easily accessible to all health professionals. The continuation and expansion of the network depends upon the renewal of this Act.

Renewing the Medical Library Assistance Act would also provide the funds to:

(1) develop and implement innovative and cost-effective methods of disseminating information;

(2) continue the consultation, education and training funds that have assisted administrators in setting up information-delivery systems and have helped personnel working in the health sciences libraries to be more efficient in performing their tasks;

(3) coordinate efforts in applied research so that technological advances can be utilized to reduce the time spent in countless health sciences libraries doing tasks that are duplicated all across the nation. This would assist each of us in containing costs.

(4) assist in developing resources to stimulate library growth and development in areas serving the rural practitioners.

It is my hope that Congress, in its efforts to improve the quality and delivery of health care in the nation will continue to recognize the significant role libraries play in the delivery of health related information and will renew the Medical Library Assistance Act for five years, a sufficient period to permit good planning.

Sincerely yours,

Lois Ann Colaianni

Lois Ann Colaianni
Director of Libraries

LAC:rt

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CONGRESSMAN PAUL C ROGERS
US HOUSE OF REPRESENTATIVES
WASHINGTON DC 20515

AS PRESIDENT AND MEMBER OF THE BOARD OF DIRECTORS OF THE ASSOCIATION OF AMERICAN CANCER INSTITUTES WE ARE WRITING TO YOU CONCERNING HR10908 WHICH RELATES TO THE RENEWAL OF THE CANCER ACT THE AACI REPRESENTS 70 CANCER CENTERS IN THE UNITED STATES AND HAS A VITAL INTEREST IN THEIR CONTINUED SUPPORT ALMOST ALL THE ADVANCES IN CANCER CARE OVER THE PAST 25 YEARS HAVE ORIGINATED IN THE CANCER CENTERS-THE CURE OF CHILDHOOD LEUKEMIA, OF HODGEKINS DISEASE AND OTHER LYMPHOMAS, THE CURES OF NUMBER OF CHILDHOOD CANCERS AND A SUCCESSFUL ADJUVANT TREATMENT OF OSTEOSARCOMA AND BREAST CANCER ARE JUST A FEW THE CREATION OF NEW CENTERS IN A NUMBER OF UNIVERSITIES HAS PROVIDED A NETWORK OF CENTERS ACROSS OUR COUNTRY THAT MAKES THESE ADVANCES WIDELY AVAILABLE TO MOST PATIENTS MOREOVER BECAUSE THE CENTERS ARE FOCI OF RESEARCH EXCELLENCE, OF HIGH QUALITY OF PATIENT CARE, OF EDUCATION FOR THE PROFESSION AND ESPECIALLY FOR COMMUNITY OUT REACH THEY HAVE BECOME THE PRIMARY INSTRUMENTS FOR RAPID TECHNOLOGICAL TRANSFER OF EMERGING INFORMATION FOR THE DIAGNOSIS AND MANAGEMENT OF CANCER INFLATION PLUS THE DILUTION OF AVAILABLE FUNDS BY THE CREATION OF NEW CENTERS HAS RESULTED IN REDUCTION OF SUPPORT FOR MOST EXISTING CENTERS IN A NUMBER OF CENTERS EFFECTIVE PROGRAMS IN CANCER CONTROL, EDUCATION AND CLINICAL APPLICATION OF RESEARCH FINDINGS ARE BEING SHARPLY CURTAILED WE WOULD STRONGLY URGE THAT IN HR10908 STEPS ARE TAKEN TO SUPPORT CENTERS AT A HIGHLY EFFECTIVE LEVEL IN THIS REGARD WE SPECIFICALLY RECOMMEND ONE CANCER ACT BE RENEWED FOR A THREE YEAR PERIOD TWO THE AUTHORIZATION AMOUNT FOR THE CANCER ACT BE RAISED TO 1.3 BILLION DOLLARS FOR FISCAL YEAR BEGINNING OCTOBER 1979; 1.4 BILLION, 1980; 1.5 BILLION FOR 1981 WE RESPECTFULLY REQUEST THAT THIS LETTER BE PLACED IN THE HEARINGS ON HR10908

DR C GORDON ZUBROD PRESIDENT ASSOCIATION OF AMERICAN CANCER INSTITUTES
666 ELM ST BUFFALO NY 14263

15:19 EST

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The
National Hemophilia Foundation
25 WEST 39th STREET • NEW YORK, NEW YORK 10018 • (212) 869-9740

March 3, 1978

The Honorable Paul G. Rogers
U.S. HOUSE OF REPRESENTATIVES
2407 Rayburn House Office Building
Washington, DC 20514

Dear Congressman Rogers:

RE: HR 10908

The Foundation is aware that your sub-committee on Health and Environment is now holding hearings on the Biomedical Research and Research Training Amendments of 1978 which would amend the Public Health Service Act by revising and extending programs of assistance of the National Heart, Lung and Blood Institute (NIH) and other biomedical research authorities.

Your February 9th statement, as reported in the Congressional Record was read with great interest and we applaud your wisdom in urging that the research training programs be extended for a three-year period.

Inasmuch as it is not feasible for the Foundation to personally present testimony, it would be appreciated if this letter indicating our views could be inserted into the record.

The National Hemophilia Foundation strongly supports your recommendation for a three-year extension for the progrmas of the National Heart, Lung and Blood Institute. As you are well aware, biomedical research is the key that will unlock the door to a better understanding of the disease problems with which we are faced. Advances made here are, and of necessity must be, the initial step that must be taken before any of these discoveries can be translated into effective health care delivery programs. A three-year extension will be able to provide NHLBI with the time so that more effective and efficient programs result. In addition, such an extention will signal the research community (upon whom the future depends) that the Congress is truly concerned about the state of the art in research, for today and for tomorrow.

The Foundation respectfully suggests that the proposed funding authorizations for NHLBI are too low, and recommends consideration of an authorization of $600 million for FY 1979 ($565 million for research and other programs and $35 million for prevention and control programs). For FY 1980, we recommend an authorization level of $690 million ($650 million for research; $40 million for prevention and control). For FY 1981, we recommend an authorization level of $795 million ($750 million for research; $45 million for prevention and control).

An Active Member of the National Health Council

The Foundation fully recognizes that financial constraints must be excercised by the Congress. However, in our opinion, you dare not jepordize the National biomedical research effort with its resultant gains for the health and well being of all Americans for the lack of proper funding.

The National Hemophilia Foundation is intimately aware of the excellence of the programs at NHLBI, since many of them do and will have a direct bearing on the quality of life that this Nation's hemophiliacs can expect. We have found in this Institute and in its Director, Dr. Robert Levy, a superb level of competence and professionalism, and yet it is understanding and responsive to the needs of hemophiliacs. We are confident that given sufficient financial support, NHLBI can fulfill an even greater role in not only assisting those who are afflicted with hemophilia, but more importantly, the nation as a whole.

We respectfully urge your thoughtful consideration of our recommendations.

Sincerely,

George J. Theobald, Jr.
Executive Director

GJT:lcw

cc: Dack W. Dalrymple, Assistant Counsel - Sub-Committee
House Sub-Committee Members

THE UNIVERSITY OF TEXAS SYSTEM CANCER CENTER

M. D. Anderson Hospital and Tumor Institute
Texas Medical Center Houston, Texas 77030

R. Lee Clark, M.D.
President

March 6, 1978

The Honorable Paul Rogers, Chairman
Subcommittee on Health and the Environment
Rayburn House Office Building 2415
U. S. House of Representatives
Washington, D.C. 20515

Dear Congressman Rogers:

I understand that hearings are presently underway on your bill H.R. 10908 which, among other things, extends the program of the National Cancer Institute. May I strongly urge your committee to raise the proposed level of authorization to at least $1.3 billion for FY '79. The authorizations presently provided by H.R. 10908 will only compensate the rate of inflation and will not allow the cancer program to continue to move forward.

As a member of the President's Cancer Panel from 1972 until 1977, I had the privilege of viewing and participating in the greatly increased national effort. Not only were there great increases in basic or fundamental research regarding molecular biology of the normal and malignant cell, but also new task forces and comprehensive cancer centers were created to adapt these new findings to the care of the cancer patient.

Our great effort now should be expanded for the first gleamings of the control of generalized or systemic cancer from which 60% of the patients die. New and better drugs applied under the control conditions of clinical research are required. These drugs are best applied in a comprehensive cancer center. Out of the 19 comprehensive cancer centers now existing many of them are just getting started and will require support to be able to become fully operational centers. Senator Muriel Humphrey has urged Senator Kennedy to increase the level of authorization for the National Cancer Program in the bill presently being considered by his subcommittee, and she has stressed the need for a second generation of anti-cancer drugs that will be less toxic and more effective. I am pleased that she has joined in our efforts, and certainly she brings a special understanding of the problems of the cancer patient. Enclosed for your information is a copy of a letter I recently wrote her.

May I also add that I am opposed to the funding of hospices, as advocated by some of my distinguished colleagues. This element of delivery of medical care does not belong in the NCI. Rather, we should be putting this money into clinical research for prevention, control, and care.

Desperately needed then to maintain the momentum is an authorization that is realistic and can be suitably used if appropriated. This becomes increasingly evident when we see a standstill budget or an actual decrease in support for cancer centers' core support and the funding of only 30% of approved grants, even then at reduced levels.

We value your strong leadership and support, and I hope you will give serious further consideration to this most critical matter.

Sincerely yours,

R. Lee Clark, M.D.
President

RLC/bl

Enclosure

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March 8, 1978

The Honorable Paul G. Rogers
Chairman, Subcommittee on Health
and the Environment
Committee on Interstate and
Foreign Commerce
House of Representatives
Washington, D. C. 20515

Re: Extension and Amendment of the National Research Service Award Act of 1974 (H.R. 10908).

Dear Mr. Chairman:

For the past two years, I have been privileged to serve as a member of the Committee established by the National Academy of Sciences to conduct studies respecting biomedical and behavioral research personnel, pursuant to Section 473 of the Public Health Service Act, as enacted by the National Research Service Award Act of 1974. I am writing you, from this perspective, to comment on H.R. 10908, the legislation now pending before your Subcommittee to extend and amend the National Research Service Award Act of 1974.

I wish to emphasize that I am writing this letter in my capacity as a private citizen, and not on behalf either of the National Academy of Sciences or of the NAS Committee. These views reflect my own personal opinions.

The following comments are set out in the same order as the provisions of the NRSA Act, and not in order of importance.

1. Sections 102, 472, and 473 of the NRSA Act should be amended to include health services research training funded by the Department of HEW through the National Center for Health Services Research. It is anomalous for the NRSA Act to include training for health services research at NIH, ADAMHA, and the Division of Nursing of HRA, but not to include the National Center for Health Services Research. In fact, the NAS Committee has been forced to consider health services research training at the National Center for Health Services Research at HRA in each of its reports.

In its 1977 Report (page 142), the NAS Committee specifically stated that "an extension of the NRSA statutory authority to include the NCHSR is warranted," and made the following recommendation:

> "Recommendation. In order to assure the provision of urgently required training funds, the Committee recommends a statutory amendment of the NRSA Act to include all research training provided by the HRA."

I am uncertain whether this form of amendment, in itself, would be sufficient to include all research training programs in health services research supported by the Department of HEW. An appropriate amendment might include a general provision bringing under the NRSA Act all other biomedical and behavioral research training in the Department.

2. Section 472(a)(3) of the NRSA Act presently permits the NAS Committee to exercise a "veto power" by determining subject areas (which the NAS Committee calls "fields") for which there is currently no need for additional research personnel. If the NAS Commitee exercises that veto power no National Research Service Awards may thereafter be made in those fields. That veto power has in fact not been exercised because of the Committee conclusions, spelled out in its 1976 and 1977 Reports, that research training in all of the broad areas (basic biomedical sciences, behavioral sciences, clinical sciences, health services research, and nursing research) as well as the fields within those areas continues to be justified, although in some cases at reduced levels.

H.R. 10908 would amend Section 472(a)(3) to eliminate this veto power of the NAS Committee. I believe that this change is unwarranted and would be a bad mistake. I have seen no justification whatever for such a change in the Act. The process established in the Act has been working very well up to now and, absent some clear and compelling reason for a change, I would strongly urge that this provision remain as it is.

The only possible reason for this amendment would be to weaken the influence of the NAS Committee and to permit the Department of HEW to make decisions with respect to research training in subject areas on the basis of subjective impression rather than objective data. During the past two years, I have found it distressing that the NIH is unable to adduce any data whatever to support its subjective impressions of areas and fields that deserve emphasis or that do not deserve additional research training. There exists within NIH a lack of coordination of research training efforts, and a resulting lack of an adequate rationale to justify the limited "research areas" specified by each Institute in the annual NRSA Announcement. Major efforts have been made by the NAS Committee to develop sound data on which such decisions can be made. The amendment proposed in H.R. 10908, which I understand was suggested by NIH, would substantially undermine these efforts of the NAS Committee.

I think it important to emphasize that at stake here, in addition to this specific provision, is the view of Congress with respect to the role and significance of the NAS Committee. If you wish the NAS Committee to take its statutory mission as seriously and importantly as it has in the past, and to attract the high caliber of scientists and science administrators that it has, then it would be extremely unwise to make any effort to weaken the role of the NAS Committee at this time. I doubt that people of the caliber who have been serving on the NAS Committee would be willing to spend the time and effort that they have spent, for no renumeration whatever, if Congress amends the law in a way intended solely to undermine their role.

One of the major purposes of the National Research Service Award Act of 1974 was to provide the opportunity for an objective evaluation of national research training needs by independent experts outside the pressures and interests of the Department of HEW and OMB and the development of reliable data on which to base research training decisions, and then to make sure that future decisions in fact reflect that evaluation and data. The amendment proposed to Section 402(a)(3) is designed to do exactly the opposite. Accordingly, I would strongly recommend that it be deleted.

3. I fully support the changes proposed by H.R. 10908 in Section 472(b)(4) of the NRSA Act, to extend predoctoral training to 5 years and postdoctoral training to 3 years, and to clarify the law that the total amount of support may extend to 8 years. Under the present wording of the law it is unclear whether support for all training, including predoctoral and postdoctoral, could exceed three years in the aggregate. The new provision will be very helpful in assuring adequate support for all qualified individuals, including minority students who will often need the full measure of support this provision will give. This change is consistent with the NAS Committee recommendations in its 1977 Report (pages 172-173 and 179).

4. Section 472(b)(5) of the NRSA Act states that National Research Service Awards shall provide for stipends and allowances for the recipients. I wholeheartedly support the change proposed by H.R. 10908, which provides for periodic adjustments to reflect increases in the cost of living. This is consistent with the recommendation of the NAS Committee in its 1977 Report (page 181).

5. Section 472(b)(5) of the NRSA Act also provides that NRSA awards to non-federal institutions shall provide for payments for the cost of "support services." The NAS Committee has heard substantial complaint about the 25 percent ceiling placed by the Department of HEW upon this cost of support services. Some institutions contend that the actual cost of support services connected with specific research training is in excess of the 25 percent ceiling, thus forcing the institution to bear these expenses in order to conduct an adequate research training program. You might therefore consider including in the House Report on this legislation language that would make it clear that actual support services in excess of the 25 percent level are expected to be reimbursed by the Department of HEW where the particular institution can show that those specific support services are reasonable for the specific training program involved.

6. Neither Section 472(b)(5) nor any other provision in the NRSA Act presently states that research training grants to non-federal institutions may include the cost of

institutional "overhead." The Department of HEW presently permits an overhead factor up to 8 percent of the Award. Once again, institutions receiving research training grants have complained that this 8 percent figure does not cover the full overhead expense reasonably related to specific training programs, thus forcing them to absorb those additional costs or to reduce the quality of the program.

This problem is apparently exacerbated by the fact that, in at least some instances, those institutions are also conducting research, as well as research training, under Federal grants, and that neither of these grants carries the full overhead. These institutions are therefore conducting both research training and actual research with Federal money, for the benefit of the public, without being provided the overhead expenses necessary to maintain the facilities needed to conduct both enterprises. If this is allowed to continue for any significant period of time, the research facilities themselves will undoubtedly deteriorate and the quality of both the training and the research will suffer. Accordingly, I recommend that you also consider language in the House Report that would specify that the Department of HEW is expected to include in any training grant award an amount that will cover the full overhead expenses reasonably related to the award, as justified by the institution, instead of the present arbitrary 8 percent ceiling.

7. Section 472(c)(1)(A)(i) of the NRSA Act, which is commonly referred to as the "payback" provision, requires individuals who are funded by National Research Service Awards to engage in specific types of activity. The NAS Committee has been concerned that this limitation excludes non-academic employment and thus that the payback provisions could be interpreted to be applicable even where the recipient of a National Research Service Award subsequently engages in very useful health research outside traditional academic employment. The NAS Committee has pointed out, for example, that with enactment of the National Health Planning and Resources Development Act of 1974, as well as legislation dealing with PSRO's and HMO's, there are non-academic health research opportunities that should be encompassed within those types of subsequent employment that do not trigger the payback provisions. Accordingly, I would urge either that the provisions of Section 472(c)(1)(A)(i) be revised to clarify this, or that appropriate language be included in the House Report in order to make this intention clear.

8. I fully support the proposed revisions of the payback provisions in Section 472(c) of the NRSA Act to the extent that they provide for full payback credit for each month of research or teaching, and each month of alternative service pays back one month of training. The present provisions unfairly penalize those who conclude not to pursue research after receiving a National Research Service Award.

9. Section 472(d) of the NRSA Act presently requires that, of the sums appropriated, not less than 25 percent shall be made available for awards provided by the Secretary under Section 472(a)(1)(A). This provision, as presently enacted, is very confusing, because Section 472 (a)(1)(A) includes pre- and post-doctoral research training of individuals at public institutions and non-profit private institutions; this could certainly be interpreted to include training grants as well as fellowships. In any event, if this continues to be interpreted by the Department of HEW to refer only to fellowships, it would create great difficulty in implementing the recommendations of the NAS Committee.

The NAS Committee has, in the course of some three years of study, worked diligently to determine the proper balance between training grants and fellowships. This balance differs not only between predoctoral and postdoctoral training but also among the various scientific areas and indeed among the various fields within those broad areas. It is unwise public policy to establish a continuing oversight function in the NAS Committee and then to constrain it by legislating a rigid floor below which the fellowship awards may not be reduced. Such a floor could result in forcing the Department of HEW to make awards of a kind that do not represent the best available information and advice on the way in which this money can most effectively be utilized in order to realize the greatest return to the American public.

As a practical matter this problem can, at least for the foreseeable future, be eliminated by changing the level of 25 percent specified in Section 472(d) to 15 percent, as is done in H.R. 10908. I see no necessity in also including a requirement that not less than 50 percent of the appropriated funds should be made available for grants under Section 472(a)(1)(B), and would prefer that this be left up to the recommendations of the NAS Committee and the decisions of the Department of HEW. As a practical matter, however, it will have no effect whatever and thus will not be harmful.

10. Numerous scientists have been concerned about the lack of "stability" in funding research training, thus leading persons who might otherwise pursue a career of research to forego this type of training in favor of areas that promise greater assurance. There are, of course, arguments on both sides of this issue. Assuming that this lack of stability is a factor, however, you might wish to consider some type of provision that would alleviate this concern. Such a provision might take one of two forms.

First, it might be appropriate to amend Section 102 of the NRSA Act, which sets forth the findings and declaration of purpose, specifically to say that it is the intent of Congress to provide continuing long-term support for research and research training, subject only to specific levels of authorization to be determined every three years and specific levels of appropriations to be determined yearly. This might help undercut the yearly OMB recommendation that all Federal funding of research training grants should be eliminated.

A second approach would be to insert such a provision directly into Section 472(d) of the NRSA Act, which sets forth the authorization levels. This might, indeed, have an even more immediate impact on the research community. I recognize that it would not have any particular substantive impact (because it, like any provision of the law, could subsequently be repealed or amended), but it nonetheless would serve at least as an expression of congressional intent that could be of some utility in assuring continuity of Federal support for research and research training.

11. With respect to Section 473 (which requires studies respecting biomedical and behavioral research personnel, now being carried out by the NAS Committee), I have one general comment before making a number of specific suggestions. As I have already mentioned, I believe that the NAS Committee has been doing a fine job with a task that is exceedingly difficult. I make that remark in response particularly to the statement of the American Society for Microbiology before your Subcommittee on March 2, 1978. ASM contended in that statement that the NAS Committee has ignored its contentions that the field of microbiology has a lack of research personnel, which justifies greater funding emphasis for that field. Actually, ASM is only one of several societies and groups who have made the identical argument before the two

public hearings held by the NAS Committee in 1977 and 1978. Representatives of many fields have contended, in very general terms, that their field is unique in needing additional manpower. None has, however, supplied convincing data and information to document that contention. In particular, ASM appeared before the NAS Committee hearing in both 1977 and 1978 to make broad and unsubstantiated generalizations, but failed to support its statements with any factual data. Only recently has it submitted supporting data, which a panel of the NAS Committee is now reviewing.

I would urge that you not fall prey to this type of special pleading. I can assure you that the NAS Committee will provide an opportunity for any interested person to appear before it to present information that bears upon this subject, and will fully review all data and information presented to it. We cannot, however, base conclusions and recommendations on broad generalizations without supporting data, and you should accept no less a standard. To change any aspect of the law based upon the statement made by ASM to the NAS Committee or to your Subcommittee would, as I have already stated, be a rejection of the very concepts on which the NRSA Act stands.

The work of the Committee is far from done. Its first task has been to begin manpower studies and analyses designed to permit recommendations about future research training needs of the country. Only now is it in a position to begin to deal with some of the broader issues raised by the legislative history of the NRSA Act and by the terms of the Act, relating to the rationale for Federal funding of the research training enterprise. The process is working well. The process is complex and cannot be done overnight. But the 1976 and 1977 Reports of the NAS Committee are direct evidence that it is proceeding in a rational, dispassionate, independent manner, and that the issues are indeed being addressed in an orderly manner rather than overlooked. Accordingly, I believe that the public is well served by the continuation, for the indefinite future, of the NAS Committee.

12. The statement of the American Psychological Association and the Association for the Advancement of Psychology before your Subcommittee on March 3, 1978, makes the cogent point that Section 473 of the NRSA Act is presently ambiguous in its coverage, in two respects. First, it does not specifically indicate whether non-academic research is

intended to be covered, as well as academic research. Second, to the extent that coverage of non-academic research is intended, it does not indicate whether this includes for-profit research (e.g., industrial research) as well as non-profit research (e.g., government and charitable institutions).

In approaching its statutory task under Section 473, the NAS Committee has attempted to determine the total number of biomedical and behavioral research scientists needed in the country, regardless of the type of employer. The NAS Committee has analyzed the academic sector most closely, largely because of the very real difficulties encountered in attempting to collect complete and accurate data on the demand for research personnel for other classes of employers.

Although Section 473 of the NRSA Act requires the NAS Committee to determine national needs for research personnel in all employment sectors, Section 472 of the Act is, as I have already pointed out, ambiguous in its intent with regard to the propriety, for payback purposes, of employment in research positions in non-academic organizations. In this respect the NRSA Act has been difficult to interpret. It would seem anomalous for the Act to require that the NAS Committee determine the need for research personnel in all employment sectors under Section 473, but then to penalize those who in fact find employment in the non-academic sectors by imposing payback requirements on them.

In a larger context, this opens up the entire question of what constitutes "research" under the NRSA Act. There is no definition of "research" in the statute or its legislative history. The NAS Committee is clear that "research" includes basic investigations into the conceptual problems of a scientific field, a type of activity characteristic of research conducted within academic institutions (and also pursued, of course, in other for-profit and non-profit institutions as well). It is far less clear that "research" includes the relatively routine testing that comprises the ordinary practice of a scientific discipline (e.g., running established toxicological or microbiological tests on specific substances) for which a doctoral degree does not appear necessary.

At its 1978 hearing, the NAS Committee heard substantial testimony about the urgent need for the training of more toxicologists in order to meet newly emerging requirements resulting from enactment of the Toxic Substances Control Act and similar regulatory legislation during the past 10 years. At the same time, the Committee was presented with no data or information to indicate that this need was for individuals to undertake fundamental research in the problems of toxicology, as contrasted with conducting and evaluating the large number of toxicological studies that are needed under the new laws. It is important to note, in this respect, that the NAS Committee specifically recognized on page 72 of its 1977 Report the need for training greater numbers of scientists in the fields of environmental health and toxicology, but concluded that there are presently no data which suggest that there are an inadequate number of research personnel in these fields.

This issue is not unique to the field of toxicology. It is entirely possible that the same situation may exist in the field of microbiology, where the NAS Committee has also been unable to discern a lack of trained research personnel but where there may well be large numbers of jobs for people who will conduct microbiological tests in such places as clinical laboratories.

Thus far, the NAS Committee has based its recommendations upon the need for research personnel who have been trained at least to the Ph.D. or equivalent, to conduct relatively basic investigations designed to advance fundamental scientific knowledge. If it is the intent of Congress to have the NAS Committee assess needs for personnel who require specialized scientific training in fields (like toxicology) where there are large employment opportunities for the application and practice of established scientific knowledge in a field, you may wish to provide guidance to the NAS Committee either through changes in the statutory language or through comments in the House Report. It is my personal belief that the NAS Committee should continue to study and report only on national needs for researchers with a Ph.D. degree to pursue fundamental scientific knowledge, whether in academic or non-academic settings and at for-profit or non-profit institutions, since it is on this vitally important and complex matter that the NAS Committee can bring to bear its special knowledge and expertise and thus make its most effective contribution.

13. You may wish to consider amending Section 473 (a)(2)(A) of the NRSA Act explicitly to include all biomedical and behavioral research training programs conducted or funded by the Department of HEW, rather than referring specifically

only to the NIH and ADAMHA programs. An alternative would be to include in the House Report specific language pointing out that all of those other programs are, in any event, also encompassed within the jurisdiction of the NAS Committee by reason of the reference in Section 473(a)(2)(B) to other current training programs.

14. You are of course aware of the difficulty created by the Internal Revenue Service ruling that National Research Service Awards are fully taxable to the recipient. Assuming that your Subcommittee does not have jurisdiction to reverse this ruling, you may wish to consider including in Section 473 a requirement that this matter be studied by the NAS Committee and that a report on it be submitted to Congress for consideration of any appropriate legislative action that may be warranted.

15. The 1976 and 1977 Reports document the present impossibility, which may well extend into the indefinite future, of determining specific scientific fields (called "subject areas" in Section 473(a)(1)(B)) in which research personnel are needed and the number of such personnel needed in each particular field. The subject is simply far more complex than was realized when the law was enacted in 1974.

Nonetheless, I see no particular need to change it at this time. As long as your Subcommittee and others in Congress realize that "fine field specification" is not possible at this time, and may well not be possible in the future, no particular difficulty is posed by the current wording of the NRSA Act. It is feasible, and the NAS Committee has made recommendations, to specify support levels for the five broad areas designated by the NAS Committee and thus to specify which of those areas require an increase or decrease in emphasis. The NAS Committee should also continue to search for particular fields within those broad areas that require emphasis or de-emphasis, and additional data may well become available that will permit greater specificity at this level as time goes on. But it is unlikely that we will soon reach the day when specific training levels can be specified for every scientific field in the biomedical and behavioral sciences.

16. The NAS Committee has made valiant, but thus far vain, efforts to come to grips with the problem of the declining number of clinical investigators. Recommendations for increasing the funding of research training for clinical

investigators have been met with a constantly declining number of applicants. It is apparent that there are more funds available than there are applicants to receive them. Thus, the problem is not the lack of emphasis being placed on this area; rather, it is the lack of attractiveness of a research career for physicians and other clinical investigators that is the problem.

I am not at all sanguine that the changes in the payback provisions in the Act will have any discernable impact on this situation. Other factors, such as the current regulatory limitations on clinical investigation and the low renumeration in relation to other aspects of the practice of medicine, would seem to be far more important. It is not feasible, however, to discuss in this letter all of the different factors involved. The NAS Committee is beginning to address these issues. In view of the importance of this matter, however, you may wish to consider including in Section 473 a specific directive for the NAS Committee to investigate all of the factors bearing upon the decline in interest in clinical investigation and making conclusions and recommendations that can be considered by your Subcommittee in the future.

17. The necessity of preparing a major report every year, as presently required by Section 473(c) of the NRSA Act, is extremely burdensome. On the other hand, I am personally troubled by the change proposed in H.R. 10908, that a report shall be made at least once every three years. I believe that the NAS Committee should be required to report its recommendations under Section 473(a)(1) not later than September 30 of each year in at least summary form, with some brief explanation, and that a more complete report on all of the NAS Committee activities should be required at least once every two years (rather than once every three years), with additional authority to issue reports on specific matters on a periodic basis at the discretion of the Committee. I believe that the NAS Committee, like any organization, fully needs a prod to make certain that it will issue reports on a timely basis so that they will be most useful to the Congress, the Department of HEW, the scientific community, and the public in general. A requirement that such reports issue only once every 3 years would not, in my judgment, serve that purpose.

* * *

In conclusion, I wish to reiterate my support both for the National Research Service Award Act and specifically for the function of the NAS Committee under that Act. A healthy tension exists between the NAS Committee and the Department of HEW, by which the American public is benefiting. I sincerely hope that H.R. 10908 is enacted with the many provisions that will strengthen the National Research Service Award Act of 1974 without weakening it by undermining the role of the NAS Committee.

Sincerely yours,

Peter Barton Hutt

Peter Barton Hutt

PBH/mh

EPHRAIM McDOWELL COMMUNITY CANCER NETWORK, INC.
915 SOUTH LIMESTONE STREET
LEXINGTON, KENTUCKY 40503

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SECRETARY

DAVID M. GOLDENBERG, Sc.D., M.D.
EXECUTIVE DIRECTOR

606-233-6541

March 10, 1978

Congressman Tim Lee Carter, M.D.
U.S. House of Representatives
Washington, D.C. 20515

Dear Congressman Carter:

You are aware that the Ephraim McDowell Community Cancer Network was established as a cancer center program, including outreach control, education, and research programs, in 1975. Since then, we have developed local District Cancer Councils in half the Commonwealth of Kentucky, instituted community-based and -directed tumor conferences, established a statewide Cancer Hopeline for public information, and revitalized the cancer research activities at the University of Kentucky. At the present time, the Kentucky General Assembly is considering a bill on cancer which would coordinate cancer activities throughout the state and provide initial funding at $ 1 million per year. I am pleased that I shared in the development of this cancer act, which has already passed the Kentucky House of Representatives by a unanimous vote. These and many more activities to combat cancer in Kentucky have emanated from support we have received from the National Cancer Institute under the existing National Cancer Act, and I feel confident that the strides we are making would not have been possible without this Act. In addition to our activities in Kentucky, we are a member of the Association of American Cancer Institutes and of the Association of Community Cancer Centers.

It is for these reasons that I would like to urge you and your colleagues in Congress to support the renewal of the National Cancer Act for a three-year period, and that the authorization amount for the cancer act be raised to at least $ 1.3 billion for fiscal year 1979, $ 1.4 billion in 1980, and $ 1.5 billion for 1981. I would appreciate your including this letter in the hearings on HR 10908.

Sincerely,

David M. Goldenberg, Sc.D., M.D.
Executive Director

A NON-PROFIT ORGANIZATION FOR CANCER CONTROL IN EASTERN AND CENTRAL KENTUCKY

NORTHERN CALIFORNIA CANCER PROGRAM
1801 Page Mill Rd., Bldg B Suite 200, Palo Alto, CA 94304, (415) 497-7431 Stephen K. Carter M.D., Director

March 16, 1978

The Honorable Pete N. McCloskey
The United States House of Representatives
305 Grant Avenue
Palo Alto, CA 94306

Dear Mr. McCloskey:

As the Director of the Northern California Cancer Program and a member of the Board of Directors of the Association of American Cancer Institutes (AACI), we are writing to you concerning HR 10908 relating to the renewal of the Cancer Act. The AACI represents 70 cancer centers in the United States which have been mandated by the Act. The Congress, the AACI, and the patient have a vital interest in their continued support.

Almost all the advances in cancer care over the past 25 years have originated in the cancer centers - the cure of childhood leukemia, of Hodgkins disease and other lymphomas, the cure of number of childhood cancers, and a successful adjuvant treatment of osteosarcoma and breast cancer are just a few. The creation of new centers has provided a network of centers across our country that makes these advances widely available to most patients. The centers are focuses of research excellence, of high quality patient care, of professional education, and especially for community outreach. They have thus logically become the primary instruments for rapid technological transfer of emerging information for the diagnosis and management of cancer.

Inflation, plus the dilution of available funds by the creation of new centers, has resulted in reduction of support for all centers. In a number of centers effective programs in cancer control, education, and clinical application of research findings are being sharply curtailed. We, therefore, strongly urge that steps be taken in HR 10908 to guarantee adequate financing to support centers at an effective level. In this regard, we specifically recommend:

1) The Act be renewed for a three year period;
2) The authorization amount for the Act be raised to $1.3 billion for fiscal year beginning October 1979; $1.4 billion for 1980; and $1.5 billion for 1981.

We respectfully request that this letter be placed in the hearings on HR 10908.

Sincerely,

Stephen K. Carter, M.D.
Director

:ja

NORTHERN CALIFORNIA CANCER PROGRAM
1801 Page Mill Rd., Bldg B Suite 200, Palo Alto, CA 94304 (415) 497-7431 Stephen K. Carter M.D., Director

March 16, 1978

The Honorable Norman Y. Mineta
The United States House of Representatives
1245 South Winchester
San Jose, CA 95128

Dear Mr. Mineta:

As the Director of the Northern California Cancer Program and a member of the Board of Directors of the Association of American Cancer Institutes (AACI), we are writing to you concerning HR 10908 relating to the renewal of the Cancer Act. The AACI represents 70 cancer centers in the United States which have been mandated by the Act. The Congress, the AACI, and the patient have a vital interest in their continued support.

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We respectfully request that this letter be placed in the hearings on HR 10908.

Sincerely,

Stephen K. Carter, M.D.
Director

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AMERICAN MEDICAL ASSOCIATION
535 NORTH DEARBORN STREET • CHICAGO, ILLINOIS 60610 • PHONE (312) 751-6000 • TWX 910-221-0300

JAMES H. SAMMONS, M.D.
Executive Vice President
(751-6200)

March 17, 1978

The Honorable Paul G. Rogers
Chairman
Subcommittee on Health and Environment
Committee on Interstate and Foreign
  Commerce
United States House of Representatives
Washington, D. C. 20515

Dear Congressman Rogers:

The American Medical Association submits the following comments on H.R. 10908, the Biomedical Research and Research Training Amendments of 1978.

H.R. 10908 extends for three years the funding for support to medical libraries, the National Research Service Awards, the National Cancer Institute, and the National Heart, Lung, and Blood Institute. In addition, certain substantive amendments to these programs are also proposed.

The AMA believes that these activities have made, and will continue to make, important contributions to professional education and to the health of our citizens. We support extending the funding for these activities for one year.

The AMA strongly supports continued research into the causes, treatment and prevention of cancer. However, we also recognize that research into other diseases must remain an essential part of our total research effort. Therefore, adequate funding must be maintained for all the Institutes in recognition of the fact that the efforts of each Institute contribute significantly to the health of our citizens. We also believe that the emphasis in the Institutes should be more on fundamental biomedical research than applied research and the construction of additional facilities.

We are pleased to see that the Director of the National Cancer Institute would be appointed by the Secretary rather than the President. We believe it is appropriate to put all Institutes on an equal footing.

We also suggest that the service obligation for recipients of the National Research Service Awards (NRSA) be changed. The law provides that individuals who receive assistance should meet their program obligations primarily by engaging in teaching or research. It is inappropriate to provide that NRSA obligations could be met by service in the National Health Service Corps, in a designated area in private practice or in an HMO. These alternatives to service in teaching or research do not appropriately relate to the purposes of the program and, in our opinion, should be discontinued.

We request that these comments supporting a one-year extension of the above programs, with recommended changes, be made part of the Subcommittee's official hearings records.

Sincerely,

James H. Sammons, M. D.

UNIVERSITY OF CALIFORNIA, LOS ANGELES

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UCLA CANCER CENTER
THE CENTER FOR THE HEALTH SCIENCES
LOS ANGELES, CALIFORNIA 90024

March 28, 1978

Honorable George Brown, Jr.
House of Representatives
House Office Building
Washington, D.C. 20515

Dear Mr. Brown:

As Director of the UCLA Jonsson Comprehensive Cancer Center, I am writing to you concerning HR 10908 which relates to the renewal of the National Cancer Act. The Jonsson Center is one of nineteen federally-designated "Comprehensive Cancer Centers" in the United States, and as such has a vital interest in their continued support. Almost all the advances in cancer care over the past 25 years have originated in these, as well as other "specialized Cancer Centers" - the cure of childhood leukemia, Hodgkins disease and other lymphomas, the cures of a number of other childhood cancers, and a successful adjuvant treatment of osteosarcoma and breast cancer are just a few. The creation of new centers in a number of universities has provided a network of centers across our country that makes these advances widely available to most patients. Moreover, because these centers are foci of research excellence, of high quality of patient care, and of education for the profession, and especially for community outreach, they have become the primary instruments for rapid technological transfer of emerging information for the diagnosis and management of cancer.

Inflation plus the dilution of available funds by the creation of new centers has resulted in a reduction of support for most existing centers. In a number of centers, effective programs in cancer control, education and clinical application of research findings are being sharply curtailed. We would strongly urge that in HR 10908 steps are taken to support centers at a highly effective level. In this regard, we specifically recommend (1) the National Cancer Act be renewed for a three year period and (2) the authorization amount for the National Cancer Act be raised to $1.3 billion for fiscal year beginning October 1979; $1.4 billion, 1980; and $1.5 billion for 1981.

We at this Center respectfully request that this letter be placed in the hearings on HR 10908.

Sincerely,

Richard J. Steckel, M.D.
Director
UCLA Jonsson Comprehensive Cancer Center

UNIVERSITY OF CALIFORNIA, LOS ANGELES

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UCLA CANCER CENTER
THE CENTER FOR THE HEALTH SCIENCES
LOS ANGELES, CALIFORNIA [illegible]

March 28, 1978

Honorable Henry Waxman
House of Representatives
House Office Building
Washington, D.C. 20515

Dear Mr. Waxman:

As Director of the UCLA Jonsson Comprehensive Cancer Center, I am writing to you concerning HR 10908 which relates to the renewal of the National Cancer Act. The Jonsson Center is one of nineteen federally-designated "Comprehensive Cancer Centers" in the United States, and as such has a vital interest in their continued support. Almost all the advances in cancer care over the past 25 years have originated in these, as well as other "specialized Cancer Centers" - the cure of childhood leukemia, Hodgkins disease and other lymphomas, the cures of a number of other childhood cancers, and a successful adjuvant treatment of osteosarcoma and breast cancer are just a few. The creation of new centers in a number of universities has provided a network of centers across our country that makes these advances widely available to most patients. Moreover, because they have become the primary instruments for rapid technological transfer of emerging information for the diagnosis and management of cancer.

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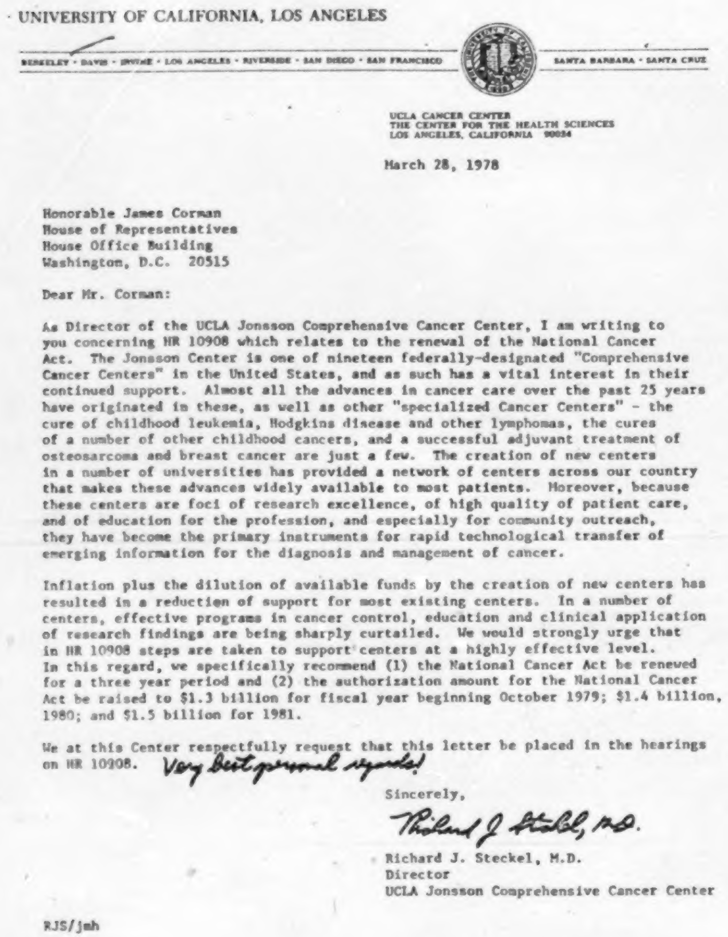
Sincerely,

Richard J. Steckel, M.D.

Richard J. Steckel, M.D.
Director
UCLA Jonsson Comprehensive Cancer Center

RJS/jmb



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UCLA CANCER CENTER
THE CENTER FOR THE HEALTH SCIENCES
LOS ANGELES, CALIFORNIA 90024

March 28, 1978

Honorable James Corman
House of Representatives
House Office Building
Washington, D.C. 20515

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We at this Center respectfully request that this letter be placed in the hearings on HR 10908. Very best personal regards!

Sincerely,

Richard J. Steckel, M.D.

Richard J. Steckel, M.D.
Director
UCLA Jonsson Comprehensive Cancer Center

RJS/jmh

[Whereupon, at 11:50 a.m., the subcommittee adjourned.]

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